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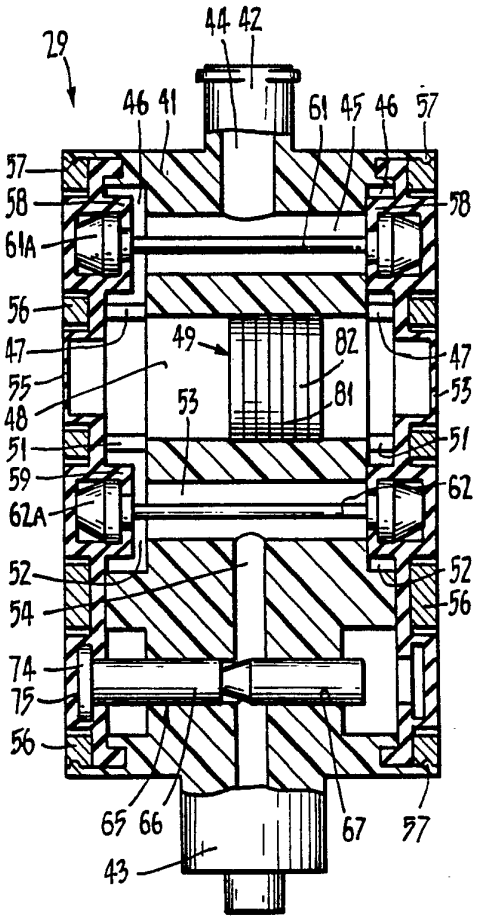
(54) Title: FLUID FLOW CONTROLLER

(57) Abstract

Fluid flow controller particularly for controlling the rate of fluid flow in an intravenous therapy system. In a first illustrated embodiment fluid flows through passages in a controller body (41) and the rate of fluid flow is measured by determining the rate of travel of a marker in the form of a piston (49) which is slidable in a central transverse passage (48) within a body (41) and is driven back and forth by the fluid. Control means comprising a microprocessor makes a comparison between the measured flow rate and a desired flow rate and adjusts a variable restrictor valve to counteract differences between actual flow rate and desired flow rate. In a second embodiment, the flow marker is a piston slidable in a transverse passage in a controller body. The piston is driven in one direction by fluid flow and returned by a solenoid. In a third embodiment, the flow marker is gas bubble formed temporarily in a flow passage by a gas injector.



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"FLUID FLOW CONTROLLER"

TECHNICAL FIELD

This invention relates to apparatus for controlling fluid flows. It has particular, but not exclusive, application in the medical field of intravenous therapy in which liquids are infused directly into the veins of a patient.

BACKGROUND ART

Intravenous therapy is widely used for infusing electrolyte (typically sodium chloride solutions) and dextrose. Nutrients and/or medications (pharmaceuticals) are often also infused by intravenous therapy using the electrolyte and dextrose as vehicles.

The traditional intravenous therapy system consists of a reservoir of saline solution and a reservoir of dextrose solution suspended on a stand and gravity-feeding, via plastic tubing fitted with a drip chamber and a variable line clamp, into the patient's peripheral or central veins.

The saline solution consists of sodium chloride (Na Cl) in sterile water with potassium chloride (KCl) being added also in many cases. The concentration of sodium chloride is usually 154 milliequivalents/litre which is referred to as NORMAL. In certain cases ½ normal (77 milliequivalents/litre) or twice NORMAL (308 milliequivalents/litre) is used. The saline

solution is usually referred to as "ELECTROLYTE".

The dextrose solution consists of dextrose ($C_6 H_{12} O_6$) in sterile water. The concentration of dextrose varies from 5% - 50% depending on patient requirements. The dextrose solution is usually referred to as "DEXTROSE".

Whilst the electrolyte and dextrose are usually both required by a patient, treatment procedures vary in that the electrolyte and dextrose are either infused simultaneously in which case they are run together from separate reservoirs into a Y junction before entering the patient's vein; or the electrolyte and dextrose are infused sequentially, in an alternating sequence. Alternatively both liquids may be mixed together in one reservoir in a solution, (for example, 3 litres of 4% dextrose and 1/5 Normal saline), but this procedure is not widely adopted.

The human venous system exhibits approximately atmospheric pressure at the heart and the pressure at any other part of the venous system depends on altitude relative to the heart. Therefore a point in a vein in the arm will become increasingly pressurized as it lowers below heart level. The extent of pressure above atmospheric will be equal to the head of blood between that point in the vein and the heart. Conversely as the point in the vein is raised above heart level the pressure at that point will become sub-atmospheric.

Since the presence of air in the bloodstream can be fatal, every endeavour must be made during intravenous therapy to prevent air embolism. In the above described traditional intravenous therapy system, air embolism is prevented by ensuring that the electrolyte and dextrose solutions enter the veins at a point of positive pressure and by ensuring that the reservoirs do not empty.

The rate of infusion of electrolyte and dextrose is determined by a doctor on the basis of observation

relating to certain patient variables.
These are typically as follows:-
Sinus heart rate
Systolic blood pressure
Diastolic blood pressure
Central venous pressure
Perfusion status (i.e. extend of blood flow to extremities)
Urine flow rate
Urine sodium concentration if available (typically it is unavailable)
Volume loss/hour of any biological fluid other than urine (i.e. bile, bleeding, fistula loss etc.)
Plasma (serum) sodium concentration (supplied from current day's Biochemistry Lab Report)
Patient's weight
Glycosuria, diuresis, anuria (This is a doctor judgement).

The way in which this data is used varies widely from doctor to doctor and is often no more than an informed guess. At best the actual determination is an empirical one taken on the basis of previous experience. Thus for the same patient different doctors could, and probably would, prescribe different electrolyte and dextrose infusion rates. Once having made a determination the doctor will issue a written instruction to a nurse who is then responsible for setting the prescribed infusion rate by adjusting the tube clamps until the number of drips falling in each of the drip chambers over a certain time interval (typically 10-20 seconds) extrapolates out to the correct flow rate. Each drop is considered by the medical profession to represent 0.06 ml but there appears to be growing awareness that drop sizes can vary over the range 0.05 to 0.07 ml and that any system which relies on counting drops therefore has an intrinsic inaccuracy factor of $\pm$ 17% due to this source alone.

In particular there is evidence to support the

belief that drop size depends on the head of available liquid, on the back pressure of the patient's venous system, on the physical properties of the actual fluid being infused as well as physical characteristics of the drip chamber. Moreover the mathematics involved in extrapolating leave considerable scope for further (cumulative) errors.

The doctor's written instruction is generally kept as a hospital record and can be called up as a legal document under an action at law.

A re-adjustment of infusion rate may be made on a very sick patient every 20 minutes. Hence it can be seen that the human involvement in administering intravenous therapy to a patient by the traditional system is quite considerable and is moreover subject to high error probability.

Over recent years increasing use has been made of intravenous pumps. Here the gravity fed system is replaced by a pump which imparts a positive pressure to the infused liquid and which usually enables the pumping rate to be set with reasonable accuracy. Some pumps also have an automatic cut-out so that the pump will switch off after a pre-set volume of electrolyte has been delivered.

Most of the pumps used on these systems are peristaltic, with delivery rate being adjusted by pump speed and total delivery being set by timing the duration of pump operation. Pumping systems have the advantage that the infusion rate can be set more easily and more accurately than with the traditional system involving the counting of drops and extrapolating out mathematically. This, together with the ability to set the pump to cut-out at a particular volume, is the biggest advantage of these pumps. On the other hand, since pumps will pump air as well as liquid, sophisticated procedures are needed to prevent air embolism which could be fatal to the patient. Also,

the pressure imparted by such pumps can cause severe extravasation (i.e. pumping of fluid into other than a vein). This could result where the cannula (i.e. needle), which normally carries the fluid into the vein is not correctly inserted into the vein or is pushed through the opposite wall of the vein. Under these circumstances fluid can be pumped into the patient's tissue, causing swelling and conditions which may be serious for the patient. The presently available pumping systems are very expensive, heavy and bulky. The weight and size of the systems is a particular problem because the pump needs to be supported on a column at the head of the patient's bed and it therefore tends to clutter the therapeutic area.

In an endeavour to embody the advantages of the traditional system (i.e. no air embolism) with the advantages of the pumping system, so-called "controllers" have recently become commercially available. These controllers use an electronic feedback system to control the gravity flow of intravenous fluids.

DISCLOSURE OF INVENTION

The present invention provides a novel type of fluid flow controller which can monitor and accurately control a flow of fluid at low flow rates whilst providing for continuous and uniform flow over the desired flow range independent of operating variables such as available fluid head, back pressure of the patient's venous system, and the physical properties of the actual fluid being infused. The controller may be incorporated in an intravenous therapy system and the invention accordingly enables the provision of an intravenous therapy system which is simple to operate and will provide precisely-controlled, air-free uniform delivery of electrolyte and/or dextrose over the required range.

The system may incorporate a novel control unit incorporating a data processor which is programmed so that all of the patient's critical variables such as sinus heart rate and systolic blood pressure can be entered into the control unit, which will then compute appropriate desired infusion rates and control the actual infusion rates accordingly.

Although the invention has arisen from a development programme aimed at solving problems in the field of intravenous therapy, the flow control apparatus in accordance with the invention can find application in other fields where it is necessary to monitor and accurately control the flow of fluids at low flow rates and it is to be understood that the invention, in its broadest aspect, is not limited to the field of intravenous therapy.

According to the invention there is provided fluid flow control apparatus for controlling a flow of fluid, comprising

means defining a fluid inlet, a fluid outlet and fluid flow means for flow of fluid from the fluid inlet to the fluid outlet;

adjustable restrictor valve means to present an adjustably variable obstruction to fluid flow through said flow means;

means to set a fluid flow marker in motion within said fluid flow means in response to a flow of fluid therein; and

control means operable to determine a rate of travel of the marker as an indication of the actual flow rate of fluid in said fluid flow means, to compare the actual flow rate with a desired flow rate and to adjust the restrictor valve means in response to the outcome of that comparison whereby to counteract differences between the actual flow rate and the desired flow rate.

Preferably, the means defining the fluid inlet,

the fluid outlet and the fluid flow means comprises a single body structure. This structure may, for example, be moulded of a plastics material.

The fluid flow marker may be a rigid piston slidable in a passage of said fluid flow means.

In one embodiment of the invention the fluid flow means comprises inlet flow director means conditionable alternatively to direct fluid flow from the inlet into one or other end of said passage whereby to cause the piston alternatively to slide along the passage in opposite directions, and outlet flow means for flow of fluid from said passage to said outlet.

In another embodiment, fluid flows through said passage from the inlet to the outlet in one direction only and there is provided power operated piston return means operable to cause the piston to undergo return strokes.

In a further embodiment of the invention the marker is a fluid piston formed as a bubble of a second fluid different from the fluid of said flow and the means to set the marker in motion is operable to form the fluid bubble piston within a passage of said fluid flow means.

In this case the second fluid may be a gas and the means to set the marker in motion in the passage may comprise a gas injector operable at spaced time intervals to inject quantities of the gas into said passage at a first location to form successive gas bubbles movable along the passage to a second location in response to fluid flow in the passage and gas retrieval means to retrieve gas from the fluid of said flow at said second location and to return it to the injector for reinjection into the passage.

The apparatus may be included in equipment for controlling the infusion rate of a liquid in an intravenous therapy system. In this case, the control means may include a data processing unit programmed to

determine said desired flow rate from a series of input signals indicative of a patient's medical condition.

The programme of the data processing unit may be such that the unit operates to determine at regular intervals whether there has been any change in said series of input signals and, if so, to condition the apparatus so as to alter the desired flow rate accordingly.

The programme may also be such that the data processing unit operates to determine whether the input signals or the operational status of above fluid flow control apparatus indicate a critical or dangerous condition for the patient and, if so, to condition the apparatus so as to prevent fluid flow therethrough and/or to trigger an alarm means.

BRIEF DESCRIPTION OF DRAWINGS

In order that the invention may be more fully explained some particular embodiments will be described in detail with reference to the accompanying drawings in which:

Figure 1 is a diagrammatic view of an intravenous therapy system incorporating flow control apparatus in accordance with the present invention;

Figures 2 and 3 are perspective views of disposable and non-disposable parts of a flow controller incorporated in the apparatus;

Figure 4 is an end view of the disposable part of the controller;

Figure 5 is a cross-section through the disposable part of the controller;

Figure 6 is a somewhat diagrammatic illustration of the assembled flow rate controller in the first said operational condition;

Figures 7 and 8 are further diagrammatic

illustrations of the controller and show the controller in the second and third said operational conditions;

Figure 9 is a block circuit diagram of electronic control equipment for the flow controller;

Figures 10 to 15 fit together as indicated in Figure 16 to form a flow chart for operation of the flow control apparatus according to a basic programme;

Figures 17 to 21 fit together as indicated in Figure 22 to form a flow chart for operation according to an extended programme;

Figures 23 and 24 show starting and purge sequences of operation;

Figures 25 and 26 show algorithms for the saline and water programmes appropriate to the mode of operation shown in Figures 17 to 21;

Figure 27 is a vertical cross-section through an alternative type of fluid flow controller constructed in accordance with the invention; and

Figure 28 is a vertical cross-section through a further alternative type of fluid flow controller also constructed in accordance with the invention.

BEST MODES OF CARRYING OUT THE INVENTION

Figure 1 shows diagrammatically an intravenous therapy system which comprises electrolyte and dextrose reservoir 21, 22 suspended above a patient from a stand 23 and providing a gravity feed of electrolyte and dextrose via tubes 24, 25 which join at Y-junction 26 into a single tube 27 through which the electrolyte and dextrose is delivered to the patient.

A pair of flow controllers denoted generally as 28 are connected into tubing lines 24, 25. These controllers operate individually to control the flow rate of electrolyte and dextrose. They comprise disposable parts 29 which are connected to the tubing of lines 24, 25 and provide fluid flow passages for the

flow of electrolyte and dextrose through these lines. The controllers also comprise non-disposable parts 31 which incorporate electrically operable components connected by respective electrical lines 32 to electronic control equipment housed within a control console 33.

As indicated in Figure 1 control console 33 may be mounted on a cabinet 34 or any other convenient support in the vicinity of the patient. As will be explained below, an output printer 35 may be used in association with the electronic control equipment.

With particular reference to Figures 2 to 6, the non-disposable part 31 of each controller comprises a housing 36 having a generally rectangular cavity or passage 37 into which the disposable part 29 can be plugged with a push fit. The disposable part 29 comprises a plastic body 41 defining a fluid inlet 42, a fluid outlet 43 and internal passages and ducts for the flow of fluid from the inlet to the outlet.

Fluid inlet 42 is formed at the upstream end of an inlet passage 44 which joins at its downstream end with the mid-part of a transverse inlet valve passage 45. Valve passage 45 has enlarged-diameter end portions 46 formed as counterbores in opposite side faces of body 41 and these end portions of the valve passage are connected via a pair of ducts 47 to the two ends of a central transverse passage 48 within which there is a slidable piston 49.

The ends of central passage 48 are also connected via a further pair of ducts 51 to the enlarged end portions 52 of a transverse outlet valve passage 53 similar to the inlet valve passage 45. One part of this valve passage 53 connects with an outlet passage 54 which extends to outlet 43.

The ends of the inlet and outlet valve passages 45, 53 and the central transverse passage 48 are closed by a pair of thin flexible rubber membranes 55

held to the opposite sides of plastic body 41 by a pair of retainer frames 56 which are snap fitted to the body at their rims 57. Membranes 55 are premoulded with pockets 58, 59 to receive enlarged head portions 61A, 62A of a pair of shuttle valve members 61, 62 located respectively within inlet valve passage 45 and outlet valve passage 53.

By movement of valve shuttle member 61 back and forth within inlet valve passage 45, the incoming flow of fluid from inlet 42 can be directed to one or other end of the central transverse passage 48 via the respective duct 47 and similar movement of shuttle member 62 within the outlet valve passage 53 enables either end of the central passage to be connected to the outlet 43 via a respective one of the ducts 51.

As seen most clearly in Figure 5, the dimensions of body 41 are such that membranes 55 tend to hold shuttle valve members 61, 62 at the extremities of their travel toward one side of body 41 so that both the inlet 42 and outlet 43 are connected to the same end of the central transverse passage 48. The shuttle valve members can be individually displaced to the other extremities of their movement by the operation of solenoids S1 and S2 (see Fig.6) mounted in the non-disposable part 31 of the flow controller to move respective solenoid plungers 63, 64 which operate on the shuttle valve members 61, 62 through one of the membranes 55. Displacement of the shuttle valve members 61, 62 distorts the membranes 55 to provide a biasing action which restores the shuttle valve members 61, 62 to their initial positions when the solenoids S1 and S2 are de-energised.

Referring further to Figs.5 and 6, restrictor valve denoted generally as 65 is actuable to provide a variable restriction to the flow of fluid to the outlet 43 via outlet passage 54. This valve comprises a plunger 66 mounted in a bore 67 extending through one side of body 41 and across outlet passage 54.

Plunger 66 can be moved back and forth by the operation of a threaded nut and spindle actuator mechanism 68 located in the non-disposable part 31 of the controller.

Actuator mechanism 68 comprises a screw threaded spindle 69 which engages a fixed nut 71 and which can be rotated and thus advanced or retracted by means of a ratchet mechanism 71A which is drivable in one direction by a solenoid S3 and in the other direction by a solenoid S4, via their respective solenoid plungers 72 and 73.

The restrictor valve plunger 66 is formed with a head 74 which fits within a pocket 75 in one of the membranes 55 so that the membrane 55 biases the plunger 66 toward a retracted position which is coincidental with a zero flow condition. The spindle 69 of the actuator mechanism operates on the plunger 66 through the membrane 55 and the bias provided by the membrane 55 ensures that the plunger 66 accurately follows forward and return movements of the spindle 69. Each of the solenoids S3, S4 and thus their plungers 72, 73 can be energised by a series of pulses and the number of pulses will accurately determine the extent of travel of spindle 69, and therefore valve plunger 66, in the selected direction.

Referring to Figs. 4 and 5 and Fig. 5A, piston 49 is a cylindrical piston which may feature a plurality of thin, parallel, circumferential or spiral striations 81 of given optical characteristics, separated by an equal multiplicity of thin, parallel, circumferential or spiral striations 82 of a different optical nature, such that an optical detection system (described below) is capable of discerning between a striation of type 81 and a striation of type 82.

The body 41 of the disposable part 29 of the flow controller features on one of its surfaces (preferably that surface facing toward the support

bracket for the non-disposable part 31 of the flow controller, and normally facing away from an operator), an area 76 suitably equipped with an optical path (such as shaped and surface finished or drilled), for use with an optical detection system, hereafter called the "piston displacement measuring system".

This piston displacement measuring system normally consists of a light source 83 and a light-detecting semi-conductor 84 (hereafter called the "light sensor"), which may operate in the visible or infrared portion of the electromagnetic spectrum, as convenient, and which are shown in principle in Fig. 9.

Movement of said piston 49 causes the light sensor 84 to sense either part of the piston's displacement via an alternation of striations with different optical characteristics, or to sense displacement of the whole piston via the different optical characteristics of the piston compared to the fluid. The output signal from optical sensor 84 will thus be a voltage of a shape resembling a square wave, whose pulse repetition rate will be proportional to the rate of movement of piston 49.

Each controller 28 has a "passive" state as illustrated in Figure 6. In this state piston 49 is located at the right hand end of passage 48 (as seen in the figure), solenoids S1 and S2 are both de-energised and both valve shuttle members 61, 62 are disposed to the left. Fluid then flows downwardly from inlet 42 and via the left hand duct 47 and the left hand end of passage 48 to the left hand duct 51 and thence through outlet valve passages 53 and 54 to outlet 43. When the controller is in this passive state, fluid will flow through it at a rate determined by the setting of restrictor valve 65.

At desired intervals, the flow rate is checked

and the setting of the restrictor valve 65 is adjusted if necessary. The flow rate is checked by causing the controller to undergo a sequence of operations as illustrated in Figures 7 and 8. This sequence is initiated by energising solenoid S1 which causes the inlet valve shuttle member 61 to move to the right and therefore to re-direct the incoming fluid through the right hand duct 47 to the right hand end of passage 48 as indicated in Figure 7.

At this state, solenoid S2 remains de-energised so that outlet 43 remains connected to the left hand end of passage 48. Piston 49 is therefore driven along passage 48 by the incoming fluid and it expels fluid from the left hand end of that passage to maintain a continuous flow of fluid from outlet 43.

At the end of the piston stroke or part thereof according to whether the whole piston displacement is to be measured or whether partial piston displacement is to be measured by means of the stripes on the piston 49 the solenoid S1 is de-energised and solenoid S2 is energised. Inlet valve shuttle member 61 then moves back to the left and shuttle member 62 is moved to the right as indicated in Figure 8 so that the incoming fluid is re-directed to the left hand end of central passage 48 and outlet 43 is connected to the right hand end of that passage. The incoming fluid then drives piston 49 through a reverse stroke to expel fluid from the right hand end of the passage 48 and thereby maintain the continuous flow of fluid from outlet 43. At the end of the return stroke solenoid S2 is de-energised and the controller returns to the passive state illustrated in Figure 6. The pressure of the fluid flowing through the controller in its passive state causes a slight deformation of the membrane 55 and this position of the piston 49 is sensed by the piston displacement measuring system thus providing an indication of normal fluid flow, as described above.

Should the flow of fluid cease (due to, for instance, emptying of the fluid reservoir) then the pressure on piston 49 will be relieved and the elasticity of the membrane 55 will move the piston 49 sufficiently to enable the piston displacement measuring system to signal an interruption of normal flow.

The rate of travel of piston 49 is a direct indication of the fluid flow rate through the controller. This rate may be determined by measuring the time taken for the piston 49 to complete its stroke in one or both directions as indicated by the piston displacement measuring system. Alternatively the rate may be determined by measuring the time taken for the piston 49 to partially complete its stroke, such measurement being achieved by means of the stripes on the piston 49, as described above. As will be more fully explained below, the electronic control equipment measures the appropriate time intervals of the piston 49 displacement or partial displacement to provide an indication of the fluid flow rate and compares this with a desired flow rate to generate a comparison signal which causes the adjustment of restrictor valve 65, if necessary, to correct any difference between the actual flow rate and the desired flow rate. If the measured flow rate is too large, restrictor valve 65 is operated to restrict flow by an appropriate amount and if the measured flow rate is too small the restrictor valve 65 is opened by an appropriate amount.

The control equipment may comprise a microprocessor 86 programmed to carry out the required monitoring and control functions (see Fig. 10). One exemplary arrangement is illustrated in Figures 9 and 10 in which Figure 9 shows diagrammatically the electrical components and contacts of one of the controllers 28 and Figure 10 shows appropriate control equipment. As indicated, the control equipment

incorporates an 8048 microprocessor 86 as the central logic element. A single input/output port suffices to transfer the flow controller signals in both directions.

Wire lines A, B, C and D of Figures 9 and 10 carry buffered output signals from the microprocessor to the two shuttle-actuating solenoids S1 and S2 and the two restrictor valve adjustment solenoids S3 and S4. The 7437 Quad Buffer (88) matches the microprocessor signals to the power requirements of the solenoids.

The signals from the piston displacement measuring system which carry information about the position and rate of movement of piston 49, are supplied directly to the input port of the 8048 microprocessor. Pull-up resistors 91 and 92 (100K OHMS each) ensure correct operation of the circuit.

The presence or absence of a disposable flow controller part 28 is relayed to the microprocessor 86 by contacts 87 via wire line E (Figs. 9 and 10). Pull-up resistor 93 (100K OHMS) ensures correct operation of the circuit.

The "desired flow rate" is programmed by the operator by means of a selecting device 89 on the control console 33. This selecting device 89 is here shown as a variable resistor (or potentiometer) of 100K OHM resistance, but it may take some other form such as a thumbwheel selector switch linked to a series of fixed resistors.

Similarly, the "maximum volume to be infused by the controller" can be set on a selecting device 90 by the operator. Again, although selecting device 90 is shown as a variable resistor, it may take some other form such as a thumbwheel selector switch.

It is preferred to program the control equipment such that the time intervals for the piston strokes or partial strokes in both directions are measured and then

averaged to provide the basis for the actual flow rate measurement. This assists in compensating for friction, delay and inaccuracies in measurement of the time intervals. The flow rate thus measured is compared with the flow rate previously selected by the operator by means of the selecting device 89 on the control console 33, as discussed above. If the actual flow rate equals the desired flow rate, automatic adjustment of the restrictor valve 65 is unnecessary. In such a case, flow continues at the original rate, as determined by the original setting of the restrictor valve 65. Measurement of flow rates will then be repeated after a waiting interval which is predetermined in accordance with the desired flow rate setting on the control console but would be typically 30 seconds for flow rates between 50 ml/hour and 600 ml/hour.

In the case of disparity between actual and desired flow rates, the restrictor valve 65 is adjusted in the appropriate direction by a signal from the control console 33. Immediately following this adjustment, a further measurement of actual flow is made. Should some disparity between actual and desired flow rates still exist, then the control console 33 will again adjust the restrictor valve 65 in the appropriate direction. This sequence will continue for 4 adjustments, after which the actual flow rate equals the desired flow rate; if after 4 adjustments the actual flow rate does not equal the desired flow rate, an alarm 94 is activated via wire line F (it is designated "ACTUAL FLOWRATE NOT EQUAL TO DESIRED FLOWRATE" and may be visual or audible).

If the desired flow rate is changed on the control console by the operator, a measurement of actual flow rate is instantly made, and flow rate is adjusted as necessary in accordance with the above described sequence of operation.

The actual flowrate, measured from time to time as described above, is integrated by the microprocessor 86. This integrated value is the actual volume infused.

A "maximum fluid volume to be infused" can be selected by means of selector 90, as described earlier. The actual volume infused is continually compared, by the microprocessor 86, with the desired maximum volume to be infused, as set by selector 90. When the correct volume of fluid has been infused, the flow of fluid is set to zero as described above, and an alarm 94 designated "infusion complete" is activated via wire line F. This alarm may be visual and/or audible.

It is possible to manually control the operation of restrictor valve 65 at all times. This could be necessary, for example, if the power supply for the control console 33 should fail, or the cable 32 to the flow controller 28 becomes disconnected. This manual control over the flow rate is achieved by means of a serrated thumb wheel 95 projecting from the bottom of the non-disposable part 31 of the flow controller (see Figure 3) and connected mechanically to the spindle 69 of valve actuator member 68.

The control console 33 features a (momentary action, spring return) button 96 (see Figure 9) marked "purge". During initial set-up of the equipment, and on subsequent occasions on which it becomes necessary to remove traces of air in the tubing or Y-junction 24, 25, 26, 27 the tubing 27 is disconnected from the patient and the purge button pushed.

This has the effect of opening restrictor valve 65 to a fast flowrate (typically 300 ml/hr), and

allowing any air in the said tubing to be flushed out. In addition, 4 measuring cycles, as described above and illustrated in Figs. 7 and 8, are initiated by actuation of the "purge" button.

The object of the 4 abovementioned measuring cycles is to purge air from ducts 47 and 51 (see Figs. 5, 6). These two ducts may not otherwise necessarily be clear of air.

Resistor 97 (100K OHM) ensures correct operation of the circuit.

The push-button 96 having been released, and the "purge" sequence having been completed, the restrictor valve 65 returns to its fully closed position and the controller resumes normal operation.

The "purge" push-button 96 is physically protected against accidental or malicious operation by standard means such as (e.g.) a flap which obscures the button 96 and must be deliberately circumvented to actuate button 96.

Under certain alarm conditions, a so-called "keep vein open", or "KVO" rate (hereafter referred to as "KVO") is required to be supplied by the controller. The purpose of such a flowrate is to prevent blockages of tubing 24, 25, 26, 27 and it is typically of the order of 1 to 5 ml/hr.

Such KVO flowrate is achieved, where necessary, by the microprocessor 86 by total closure of restrictor valve 65, followed by 2 pulses of the opening solenoid S3.

A b.c.d. output connector on the control console supplies a signal which can be applied via a b.c.d. bus 98 to a suitable documentation device, such as the output printer 35 shown in Figure 1, in order to provide a hard copy of actual flow rate at any time. It would also be possible to extract condensed information about a period of fluid therapy in this

fashion, or to enter the information into a computer. The signals derived for the hard copy or computer could also be used to provide a remote display of information.

The body of each controller 28 may be made of a transparent plastics material and the whole of the floating piston 49 shall be optically characterised to provide not only a sensing indication of fluid flow, as described above, but also a visual indication of fluid flow. Likewise, the restrictor valve 65, the two valve shuttle members 61 and 62, and the actuator mechanism spindle 69 shall be brightly coloured to provide a visual indication of the operation of the disposable part. Thus, if the control equipment should be inoperative for any reason, it would be possible to time the movement of the piston 49 by visual observation and manually adjust the restrictor valve 65 accordingly.

Instead of receiving the desired flow rate as a direct operator input, the microprocessor 86 of the control equipment may additionally be programmed to determine a desired flow rate from a series of input signals indicative of a patient's medical condition. The program may also be such that the microprocessor operates to determine whether the input signals indicate a critical or dangerous condition for the patient and, if so, to condition the fluid flow controllers so as to prevent fluid flow therethrough and/or to trigger an alarm means.

The operation of the illustrated apparatus is not influenced by the patient's venous pressure nor by the viscosity of the fluids, nor by the heads of fluid presented at the input sides of the flow controllers

28, nor by ambient temperature nor by any other foreseen operating conditions. Uniform continuous flow is provided over the whole fluid flow range which is typically 1-600 ml/hr. Each flow controller 28 is in a passive state at all times other than when fluid flow is measured and failure of the control console 33 results in maintenance of the previously established flow rate.

This is in direct contrast to most devices currently available for purposes of fluid infusion control. In previous devices, a failure of the power source or the control device normally results in either zero, or an uncontrolled and excessive fluid flow rate, both of which conditions represent a potential hazard to the patient. Moreover, the low power consumption of the equipment in its normal operating state, and its small number of moving components contribute to its reliability and potentially long operating time when powered from a portable power source. The small physical size of the flow controller is advantageous in that it reduces bulk in the immediate vicinity of the patient.

Figure 27 illustrates an alternative fluid flow controller which can be incorporated in an intravenous therapy system of the kind described in detail above. This controller comprises a disposable part 111 which provides a fluid flow passage for the flow of the fluid to be monitored and controlled. In an intravenous therapy system, this fluid is often dextrose or electrolyte, but may be any of a number of fluids.

The controller also comprises a non-disposable part 112 which incorporates electrically operable components which may be connected to electronic logic and control equipment as in the previous embodiment.

The disposable part 111 comprises a plastic body 113 defining a fluid inlet 114, a fluid outlet 115,

and internal passages for the flow of fluid from the fluid inlet to the fluid outlet.

Fluid inlet 114 is formed at the upstream end of an inlet passage 116, which delivers fluid to one end of a transverse passage 117 housing a slidable piston 118. The other end of transverse passage 117 is connected with an outlet passage 119 extending to the fluid outlet 115. A restrictor valve, denoted generally as 121, is actuable to provide a variable restriction to the flow of fluid to outlet 115 via outlet passage 119.

The inlet end of transverse passage 117 is closed by a thin flexible membrane 122. The other end of transverse passage 117 is closed by a second membrane 123. These membranes feature moulded pockets, designed to receive heads 120 formed at the ends of two rods 130 which project, one from each end of piston 118. The membranes are held to the opposite sides of plastic body 113 by respective retainer frames 124 and 125, which are snap-fitted to the plastic body 113 at their rims.

Restrictor valve 121 may embody one of several designs. One such design comprises a valve needle or plunger 126 disposed within a tubular extensible sheath 128, which may be moulded integrally with membrane 123. The valve plunger 126 and its enveloping sheath 128 are disposed within a bore 129 extending through one side of plastic body 113, and across outlet passage 115. Plunger 126 can be moved back and forth by the operation of a threaded nut and spindle actuator mechanism 131 located in the non-disposable part 112 of the controller.

Actuator mechanism 131 comprises a screw-threaded spindle 132, which engages a fixed nut 133, and which can be rotated, and thus advanced or retracted by means of:

1. a ratchet mechanism 134, which can be

driven in one direction by a solenoid 135, and in the other direction by a solenoid 136; or

2. the same ratchet mechanism 134, but alternatively driven in either direction by a reversible stepper motor; and

3. a knob engaging with said spindle 132, when said knob is actuated, and protruding from the non-disposable part 112. Said knob is, in intravenous therapy applications, referred to as the "manual override control", and allows hand adjustment of actuator mechanism 131 without the intervention of the electronic logic and control equipment.

Each of the solenoids 135 and 136 can be energized by a series of pulses. The particular solenoid energized will determine the direction of travel of spindle 132. The number of pulses applied to said solenoid will accurately determine the extent of travel of spindle 132, and therefore of valve plunger 126, in the selected direction. Spindle 132 may alternatively be driven in each direction by a reversible stepper motor.

The spindle 132 of the actuator mechanism operates on plunger 126, and the bias provided by the elasticity of the sheath ensures that the plunger accurately follows forward and return movements of the spindle.

When valve plunger 126 is in its retracted position, the extensible sheath 128 is relatively thick, and said sheath seals the transverse bore 129. As the plunger 126 is moved from this zero flow position, the sheath is stretched so that its side wall becomes thinner, thereby opening the previously sealed bore, so that flow of fluid can occur through the outlet passage.

The magnitude of fluid flow through the outlet

passage is thus directly controllable via actuator mechanism 131, which controls stretching of sheath 128 around plunger 126.

The non-disposable part 112 of the controller also includes a solenoid 138, which is operable in such a way as to control the position of piston 118, in the manner described below.

Piston 118 is of hollow D-shaped cross-section, and has on its flat surface a number of parallel stripes (which are distinguishable to an optical detection system) from which it is possible to obtain information about the position and velocity of said piston.

The rear of the plastic body 113 carries a small, suitably shaped and surface-finished lens at the level of piston 118. This lens carries light from a suitable light source (such as a Light Emitting Diode) to the piston 118. This light is reflected, by said stripes on said piston 118, back through the lens to a light-sensitive device (such as a photo-transistor) which picks up the reflected light signals. The direction of fluid flow under steady-state conditions is shown by the arrows in Figure 27 .

Piston 118, having virtually a fluid-tight seal around its circumference, is forced downstream in passage 117 by the pressure of fluid due to the head of fluid above fluid inlet 114. Provided the head of fluid is sufficient, membrane 122 will distend slightly. The position and rate of movement of said piston 118 are measured by the optical detection system.

Should the flow of fluid ease (for instance, due to emptying of the fluid reservoir), then the pressure on the floating piston 118 will diminish as the fluid empties. The elasticity of membranes 122 and 123 will then return the floating piston to a

position somewhat downstream from said piston's normal operating position. The piston's new position is detected by the optical monitoring system which, under normal flow conditions (i.e. when the head of fluid is sufficient to slightly distend membrane 122) is aligned with a stripe on piston 118 near said piston's upstream extremity.

In order to initiate a flow rate measurement cycle, the optical system is de-activated, and solenoid 138 is pulsed. This causes floating piston 118, by means of solenoid push rod 140, to be moved to the upstream limit of its movement in passage 117. The duration of the pulse to solenoid 138 is just sufficient to transfer the piston 118 to the limit position. Cessation of the pulse causes immediate and full retraction of solenoid push rod 140. This allows piston 118 to commence downstream travel along passage 117 under the influence of fluid pressure.

The optical detection system is activated simultaneously with the cessation of the pulse applied to solenoid 138, or else the output of the detection system is ignored during solenoid activation. This allows the optical system to address the stripes on floating piston 118, as the piston travels downstream, and thus determine the velocity of said piston. The piston velocity is directly proportional to the rate of passage of differently coloured stripes past the optical detector, and thus also directly proportional to the repetition rate of electrical pulses appearing at the output of the optical detector.

The electrical signals indicative of the measured flow rate are passed to electronic logic and control equipment as described in the previous embodiment. The logic and control equipment compares the measured flow rate with a preset "desired" flow rate. Should a disparity exist between the actual and desired flow rates, the logic and control equipment

may pulse either solenoid 135 or solenoid 136, or energize a stepper motor, in such a manner as to adjust restrictor valve 121 in the appropriate direction, and thus minimize said disparity. Details of a possible version of such logic and control equipment are fully described in the earlier application and need not be repeated.

Figure 28 illustrates an alternative type of controller which incorporates a gas injector system to inject gas into a flow of fluid to be controlled. The gas injector system forms bubbles which serve as markers whose movement can be detected by an optical system, thus allowing a measure of fluid flow rate to be obtained.

The controller illustrated in Figure 28 comprises a disposable part 141 and a non-disposable part 142. The disposable part 141 comprises a plastic body 143, which has a fluid inlet 144, and a fluid outlet 145. Fluid enters via a length of plastic tubing 146, which may be integral with body 143, and which may incorporate, at the fluid reservoir end, a standard perforator 147 which is suitable for piercing and making a watertight connection to the closure devices of any of the commonly used fluid reservoirs such as a plastic bag, a plastic bottle or a glass bottle. Alternatively, fluid inlet 144 may take the form of a female standard so-called "Luer" connector, which could then be connected to any of a number of configurations of so-called "standard administration sets". Fluid exits via a length of plastic tubing 148, which may be integral with body 143, and which may terminate in a male "Luer" fitting 149. The male "Luer" fitting facilitates connection to an intravenous cannula. An alternative arrangement would be one in which fluid outlet 145 takes the form of a male "Luer" connector.

Fluid flows from inlet 144 downwardly through a passage 151, which may contain a floating plastic plunger 152. The fluid discharges as successive drops from the lower end of passage 151 into the bottom of a large chamber 153. The fluid collects as a reservoir 154 at the bottom of chamber 153, and discharges from this reservoir to outlet 145 via an outlet passage 150.

One side of plastic body 143 is fitted with a flexible membrane 155 which closes chamber 153, and which is held to the plastic body 143 by a retainer frame 156. A body of air is trapped within chamber 153 above the liquid reservoir. An injector, denoted generally as 157, is provided to periodically inject a small quantity of air from this chamber into fluid passage 151 to form a bubble which serves as a marker, and which is driven downwardly along passage 151 by the fluid flowing through that passage. The period between injections is always long enough so that the actual fluid flow rate is not significantly altered by the bubbles in the stream at any one time.

Injector 157 comprises an injector passage 158 which extends from chamber 153 to passage 151, and which is fitted with a one-way air valve, denoted generally as 159. Air can be forced through one-way air valve 159 from the chamber 153 into the passage 151, but not vice versa. Said one-way air valve comprises a plastic stem 179, which is sheathed by a thin rubber tube 180. Said stem 179 is of D-shaped cross-section throughout a major part of its length, but has a cylindrical boss at that end of it which is remote from chamber 153. The rubber tube 180 is a tight fit on said head, but can be stretched by air forced along the segmental gap between the tube and the D-shaped part of the stem, thus permitting exhaustion of air into passage 151.

The entrance to injector passage 158 within chamber 153 is surrounded by a flexible cup 160 moulded

integrally with the rubber membrane 155. This cup can be forced against the side wall of chamber 153 by actuation of solenoid 161, which is disposed within the non-disposable part 142 of the controller, and which is fitted with a solenoid plunger 162. The plunger 162 acts against the respective part of membrane 155. This causes flexible cup 160 to entrap a small metered quantity of air, and to force that quantity of air through the non-return valve 159, to form a small bubble in the liquid stream within passage 151.

Alternatively, the injector mechanism could consist of a length of flexible hollow tubing material which connects chamber 153 to the exit of injector passage 158, and which is partly disposed along one outside wall of plastic body 143. The tubing could be squeezed (in one direction only) in what is generally referred to as "peristaltic" movement, by an agency such as a motor with a roller cam attached to it. This action would force a small metered quantity of air into the fluid stream within passage 151, in a similar manner to the injector arrangement just described.

Alternatively, any other known form of positive displacement pump could be used to inject, into passage 151, the small metered quantity of air which forms the bubble used for measurement as described below.

The rate of movement of each bubble (generated by one of the methods just described) along passage 151 is measured by two optical detectors 163 and 164, spaced along that passage. These may each comprise a Light-Emitting Diode (LED) emitter at one side of the passage, and a receiver (such as a photo-transistor) at the other side of the passage to detect radiation transmitted by said emitter.

A restrictor valve generally denoted as 165 is actuable to provide a variable restriction to fluid

flow to the outlet via outlet passage 145. This valve comprises a plunger 166, mounted in a bore 167 which extends through one side of body 143 and into the outlet passage 150. The valve plunger is surrounded by an extensible rubber sheath 168 which may be moulded integrally with membrane 155. The valve plunger operates in much the same manner as the restrictor valve plunger in the previous embodiment. Plunger 166 can be moved into sheath 168 by the operation of a threaded nut and spindle actuator mechanism, denoted generally as 171, in the non-disposable part 142 of the controller and it is returned by the elasticity of the sheath as before.

Actuator mechanism 171 comprises a screw-threaded spindle 172, which engages a fixed nut 173, and which can be rotated, and thus advanced or retracted, by means of a ratchet mechanism which is drivable in one direction by a solenoid 174, and in the other direction by a solenoid 175. Alternatively, the ratchet mechanism is drivable in each direction by a reversible stepper motor.

It is a feature of this design that the passages 183 and 150 are larger in diameter than the bore 167. That part of bore 167 between passages 183 and 150 therefore acts as an orifice whose area is determined by the degree of transverse contraction of sheath 168.

It is also a feature of the restrictor valve 165 that if the disposable part 141 is accidentally or deliberately separated from the non-disposable part 142, the flow of the fluid is automatically totally shut off by the elasticity of sheath 168. This is one of a number of "fail-safe" features.

The zero flow condition of the restrictor, as set by the actuator, is made known to the logic/control circuitry by a set of contacts 178 which close when the restrictor attains said condition.

Optional float 152 incorporates a long

tail-section which will bridge the optical detectors 163 and 164 in the event that the fluid supply runs out. In these circumstances, the float will seat against a tapered section of passage 151 to seal that passage against ingress of air. The density of said float is less than that of the fluid, so that in normal operation, it floats in the fluid.

The direction of fluid flow is shown by the arrows in Figure 28 . The float does not impede the flow of fluid, and is retained in passage 151 by a small circumferential projection 170.

The fluid proceeds down the fluid channel past the optical sensors, and finally forms a drop at a specially shaped orifice 169 in the roof of the chamber 153. The drop of fluid at this point will be visible to the operator through the transparent front of the valve. All other parts of the valve are constructed of opaque material, with the exception of one area which allows the operator to observe the extensible restrictor sheath168, which is made of coloured material.

At the bottom of chamber 153, the drop combines with a further quantity of fluid, which forms the reservoir 154. The actual volume of fluid in this reservoir 154 will depend on the volume of air trapped during initial purging of the system as described below.

The volume of fluid in the reservoir can also be influenced by pressure on membrane 155. This action is analogous to that in so-called "flexible pump chambers" which optionally form part of commonly available standard intravenous dripsets. For this purpose, a mechanical link 181 transmits manual pressure from the operator's hand on a suitably shaped knob on the outside of the non-disposable part 142, to the membrane 155, thus distorting said membrane.

Pressure on knob 181 by the operator increases

air pressure inside chamber 153, forces air out through fluid outlet 145 into the fluid supply reservoir above, and pushes more fluid from said supply reservoir down into chamber 153, thus raising the level of fluid in said chamber. The fluid then proceeds past the variable restrictor 165 to exit the valve at a rate of flow determined by the setting of said restrictor.

Should the fluid in the reservoir 154 become totally depleted, then a ball 177, whose density is chosen such that it normally floats on the fluid constituting reservoir 154, will automatically position itself athwart fluid outlet passage 150, blocking the fluid outlet passage, and thus preventing the transmission of air down that passage.

In order to encourage ball 177 to block fluid outlet passage 150, the floor, or lower portion of chamber 153 slopes toward the fluid outlet passage. The dimensions and design of chamber 153 are such as to prevent entrapment of ball 177 in the upper portion of said chamber, should disposable item 141 be accidentally or deliberately inverted.

A flow rate measurement cycle is initiated by activation of solenoid 161. The solenoid is activated (typically) by a 5 Volt, 100 millisecond pulse, which causes the plunger 162 of the solenoid to act, through the rubber membrane 155, on the integrally moulded rubber cup 160. The sides of this cup deform slightly, and the lip of the cup forms an airtight seal with the body 143. The air within the cup is compressed slightly, and escapes, via the non-return valve 159, into the fluid stream in the form of a small bubble.

Rubber cup 160 is so designed that the bubble will always exceed in size, by a factor of three, a sphere whose diameter equals the bore of the fluid

channel in the vicinity of the optical elements 163 and 164. (The bore, in this region, is of the order of 1.0 millimeter diameter). This ensures retention of the bubble against the force of buoyancy by means of the squashing effect and friction on the walls of the fluid channel, thus preventing fluid from flowing past the bubble.

The bubble formed as described above is prevented from re-entering the air reservoir 154 by the non-return valve 159, and is prevented from migrating upwards against the fluid flow (under the effect of buoyancy) by friction. The bubble will in fact be swept along with the fluid at the same speed as the fluid flow, and will pass the first optical sensor 163. Its passage will be noted by the logic and control circuitry (i.e. the microprocessor).

The same bubble will subsequently pass the second optical sensor 164, where its presence is again noted by the microprocessor. The rate of fluid flow (which is identical to the speed of passage of the bubble) is then computed from the time interval between the two optical sensor outputs, knowing their separation distance and the exact volume of the bore between the said two optical sensor positions.

The bubble, after passing the second optical detector, next passes, together with the fluid, through the drop-forming orifice 169. Here, drops are formed which can be used as a rough guide to flow rate. For this purpose, the section of the plastic body 143 in which there exists a clearly formed drop is transparent, although the actual drop-forming orifice 169 is not visible to the operator. Thus the operator can view drops, but not bubbles.

At some state between the formation of the drop, and the recombination of the drop with the reservoir of fluid, the air contained within the bubble is expelled, and combines with resident air in the chamber

153. Thus the air bubble system forms a recirculating closed-loop device.

The controller of Figure 28, is used with electronic logic and control equipment of the same kind as described for the previous embodiments. This equipment compares the measured flow rate with a preset "desired" flow rate and, in the case of a disparity between the two, pulses one of the solenoids of the restrictor actuator mechanism (or activate a stepper motor) in such a fashion as to adjust the restrictor in a direction appropriate to reducing the disparity.

In this embodiment, the control equipment may include a "purge" button. During initial setup of the equipment, and on subsequent occasions on which it may become necessary to clear air in the tubing, this "purge" button is pushed. This has the effect of opening the restrictor 165 to a substantial flowrate whilst the "purge" button is depressed. When said button is released and the purging sequence has been completed, the restrictor 165 returns to zero flow, which is detected by means of contacts 178, before automatically resuming a position commensurate with the desired flow setting.

Alternatively, the purging arrangement could be mechanical, and could result in the whole solenoid/push rod (or stepper motor/push rod) assembly which actuates restrictor 165, being pushed forward against spring tension to allow the increased flowrate required to purge the fluid lines of air. Release of the button would result in immediate re-establishment of the previously prevailing flowrate.

It is possible to manually control the operation of the variable restrictor valve 165 at all times. This would be of special importance in certain situations (e.g. if the control console or the controller itself fail to operate correctly, or if the cable to the logic and control equipment becomes disconnected). Such manual control over flow rate is

achieved by means of a serrated thumbwheel 176 situated at the bottom of the non-disposable part 142, and connected mechanically to the spindle 172, or alternatively engaging with spindle 172 when the thumbwheel is actuated.

In the apparatus illustrated in Figure 28 , the air bubbles are injected into the fluid stream by a mechanically actuated injector system. However, it would be possible to provide an alternative system, in which the fluid flow passage converges to a bore of small diameter at the injector point. This creates a Venturi suction effect which is sufficient to draw gas into the fluid stream through a simple suction tube. The suction tube could draw air from an air trap in the fluid flow passage downstream from the Venturi nozzle. The air trap could take the form of an inverted U-shaped bend in the fluid flow passage, of such proportions that the air is trapped in the upper part of the bend. To this end, the upper part of the bend could be extended upwardly to provide a large air space above the fluid flowing around the lower part of the bend. The variable fluid flow restrictor could be disposed either downstream or upstream from the air trap.

A further variation of this system would provide two such Venturi systems as have just been described, but of different dimensions, and switched in such a way as to allow optimal fluid flow detection over a very large range of flow rates.

INDUSTRIAL APPLICABILITY

Fluid flow controllers constructed in accordance with the invention need not necessarily be used in intravenous therapy equipment but can find application in other medical or non-medical fields where it is necessary to monitor and accurately control the flow of fluids at low flow rates.

CLAIMS

1. Fluid flow control apparatus for controlling a flow of fluid, comprising

means defining a fluid inlet, a fluid outlet and fluid flow means for flow of fluid from the fluid inlet to the fluid outlet;

adjustable restrictor valve means to present an adjustably variable obstruction to fluid flow through said flow means;

means to set a fluid flow marker in motion within said fluid flow means in response to a flow of fluid therein; and

control means operable to determine a rate of travel of the marker as an indication of the actual flow rate of fluid in said fluid flow means, to compare the actual flow rate with a desired flow rate and to adjust the restrictor valve means in response to the outcome of that comparison whereby to counteract differences between the actual flow rate and the desired flow rate.

2. Fluid flow control apparatus as claimed in claim 1, wherein the means defining the fluid inlet, the fluid outlet and the fluid flow means comprises a single body structure.

3. Fluid flow control apparatus as claimed in claim 1 or claim 2, wherein the marker is a rigid piston slidable in a passage of said fluid flow means.

4. Fluid flow control apparatus as claimed in claim 3, wherein the fluid flow means comprises inlet flow director means conditionable alternatively to direct fluid flow from the inlet into one or other end of said passage whereby to cause the

piston alternatively to slide along the passage in opposite directions, and outlet flow means for flow of fluid from said passage to said outlet.

5. Fluid flow control apparatus as claimed in claim 4, wherein the outlet flow means is conditionable alternatively to connect said one or other end of said passage with said outlet.

6. Fluid flow control apparatus as claimed in claim 5, wherein the inlet flow director means comprises a first pair of fluid ducts communicating one with each end of said passage and a first solenoid operated valve to connect the inlet alternatively with one or other of those ducts, and the outlet flow means comprises a second pair of fluid ducts also communicating one with each end of said passage and a second solenoid operated valve to connect the outlet alternatively with one or other of the ducts of said second pair.

7. Fluid flow control apparatus as claimed in any one of claims 4 to 6, wherein the control means operates to control the conditions of the inlet and the outlet flow means such that at regular intervals the apparatus is changed from a first condition in which the fluid from the inlet is directed to one end of said passage, the outlet is connected to that same end of the passage and the piston is located at the other end of the passage to a second condition in which the fluid from the inlet is directed to said other end of the passage while the outlet is connected to said one end of the passage whereby the piston is driven by the incoming fluid to said one end of the passage and drives fluid through the outlet; then to a third condition in which fluid from

the inlet is directed to said one end of the passage while the outlet is connected to said other end of the passage whereby the piston is driven by incoming fluid back to said other end of the passage and drives fluid through the outlet; and then back to said first condition.

8. Fluid flow control apparatus as claimed in claim 7, wherein the control means includes timing means to measure a time of travel of the piston in one or both of its directions of travel in order to provide said indication of the actual fluid flow rate.

9. Fluid flow control apparatus as claimed in claim 3, wherein fluid flows through said passage from the inlet to the outlet in one direction only and there is provided power operated piston return means operable to cause the piston to undergo return strokes.

10. Fluid flow control apparatus as claimed in claim 9, wherein the piston return means comprises a solenoid actuated plunger.

11. Fluid flow control apparatus as claimed in claim 9 or claim 10, wherein the control means includes timing means to measure a time of travel of the piston in said one direction of fluid flow.

12. Fluid flow control apparatus as claimed in claim 1 or 2, wherein the marker is a fluid piston formed as a bubble of a second fluid different from the fluid of said flow and the means to set the marker in motion is operable to form the fluid bubble piston within a passage of said fluid flow means.

13. Fluid flow control apparatus as claimed in claim 12, wherein said second fluid is a gas and the means to set the marker in motion in the passage comprises a gas injector operable at spaced time intervals to inject quantities of the gas into said passage at a first location to form successive gas bubbles movable along the passage to a second location in response to fluid flow in the passage and gas retrieval means to retrieve gas from the fluid of said flow at said second location and to return it to the injector for reinjection into the passage.

14. Fluid flow control apparatus as claimed in claim 13, wherein the control means includes timing means to measure the rate of travel of the bubbles in order to provide said indication of the actual fluid flow rate.

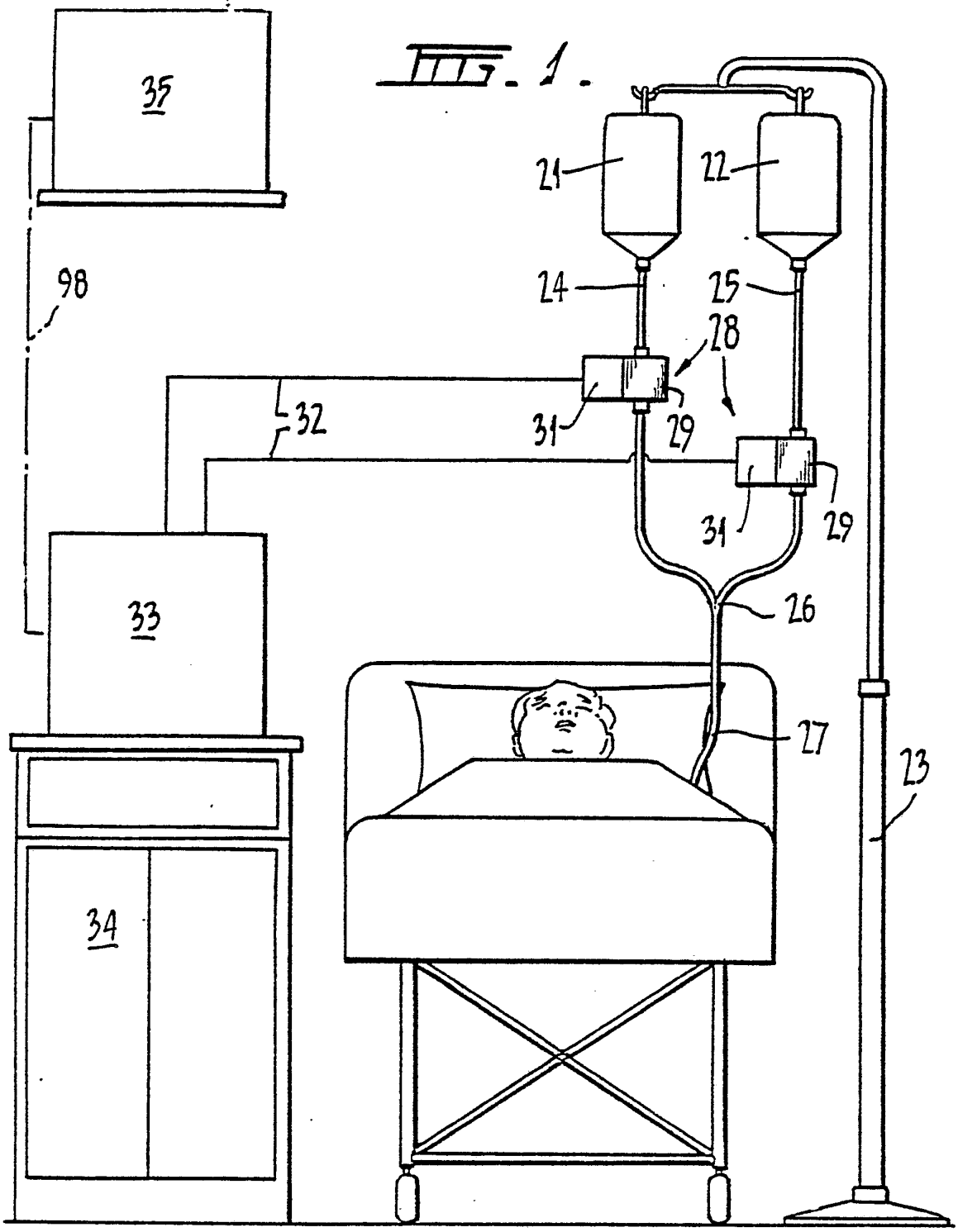
15. Fluid flow control apparatus as claimed in claim 13, wherein the control means includes timing means to measure the rate of travel of said gas bubbles along the passage.

16. Intravenous therapy apparatus comprising fluid flow control apparatus as claimed in any one of the preceding claims for controlling the infusion rate of a liquid to a patient, wherein the control means of said fluid flow control apparatus includes a data processing unit programmed to determine said desired flow rate from a series of input signals indicative of a patient's medical condition.

17. Intravenous therapy apparatus as claimed in claim 16, wherein the programme of the data

processing unit is such that the unit operates to determine at regular intervals whether there has been any change in said series of input signals and, if so, to condition the fluid flow control apparatus so as to alter the desired flow rate accordingly.

FIG. 1.



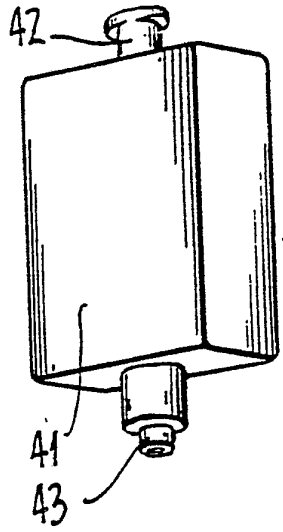


FIG. 2.

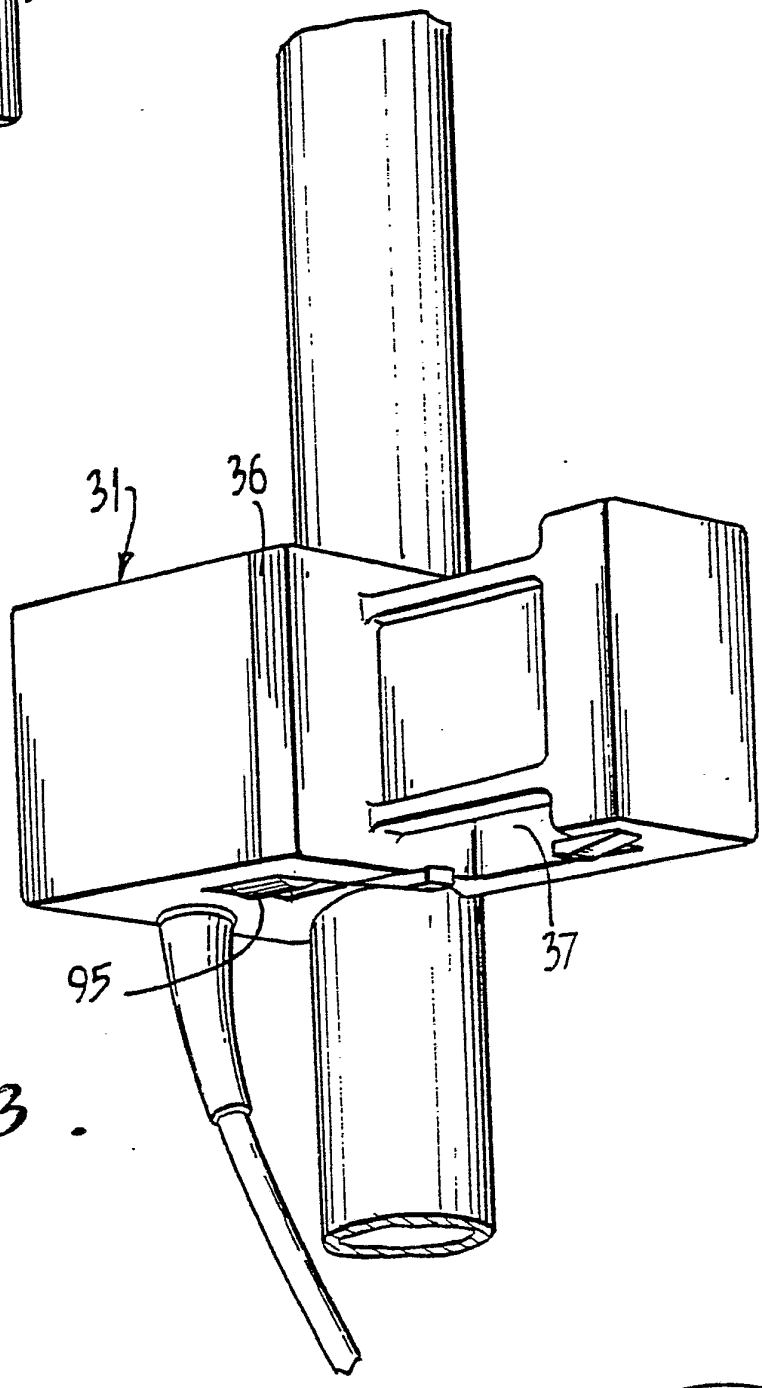


FIG. 3.

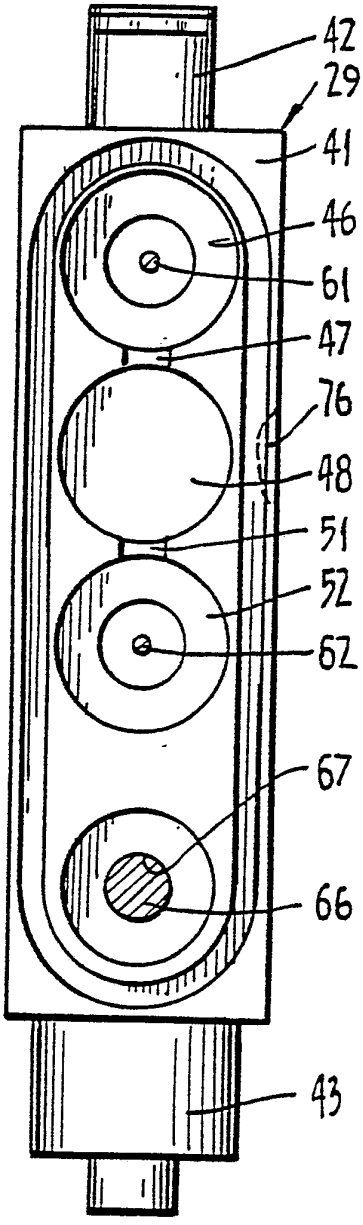


FIG. 4.

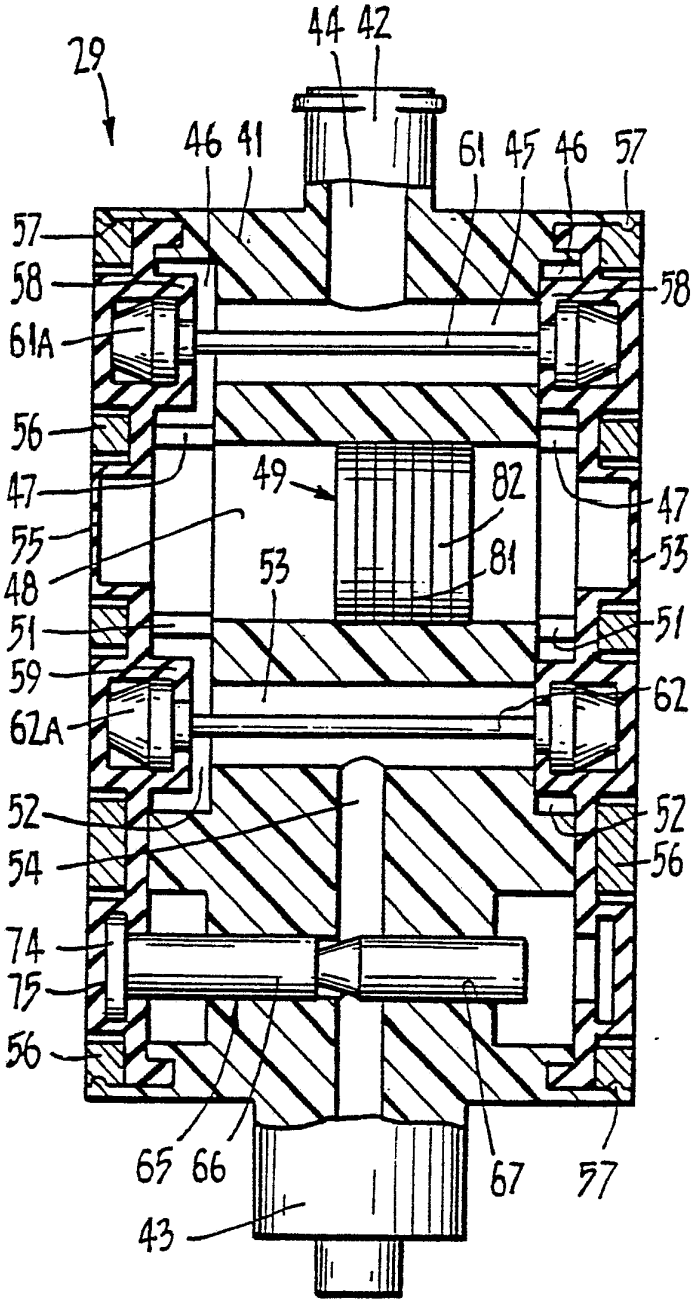


FIG. 5

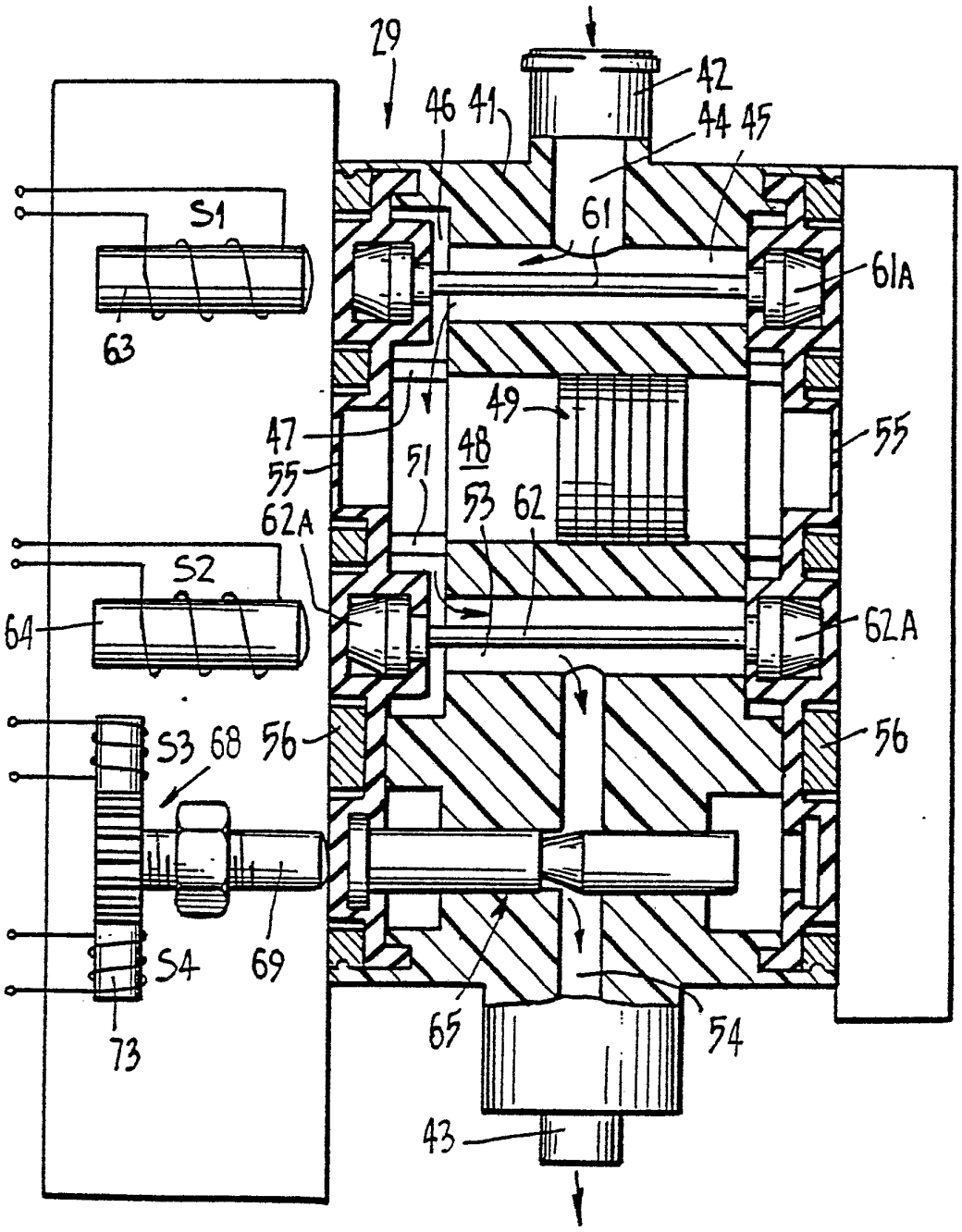


FIG. 6.

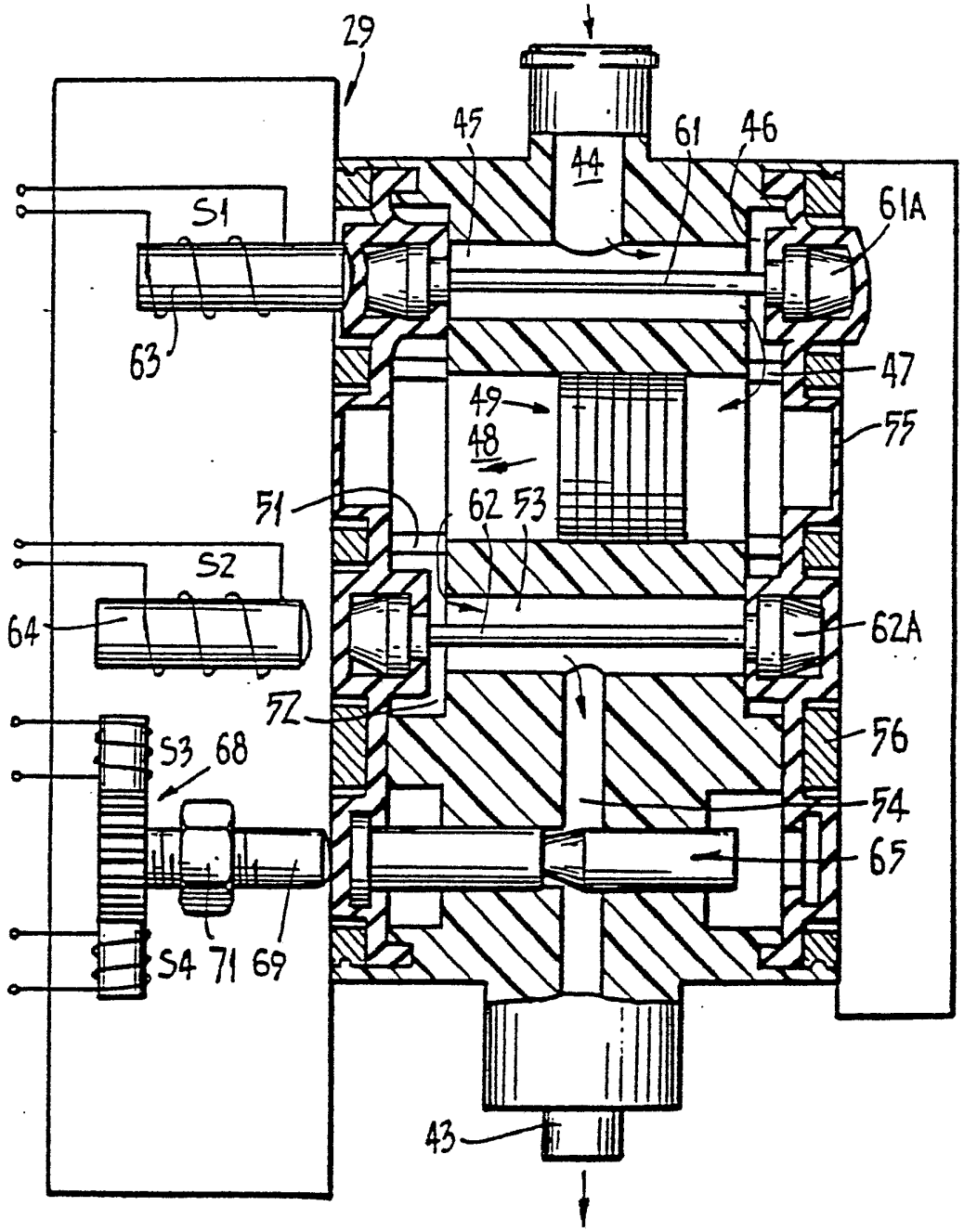


FIG. 7.

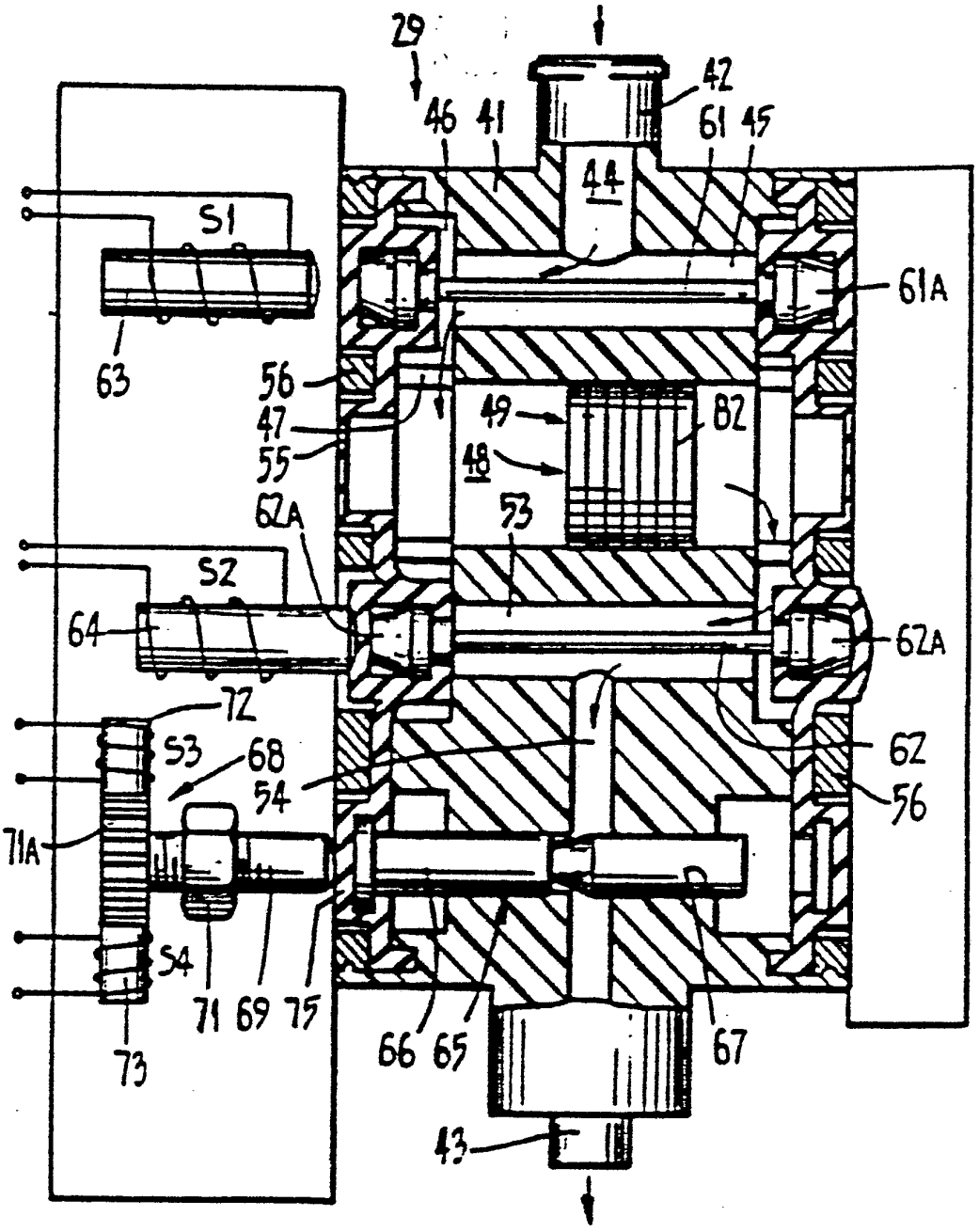
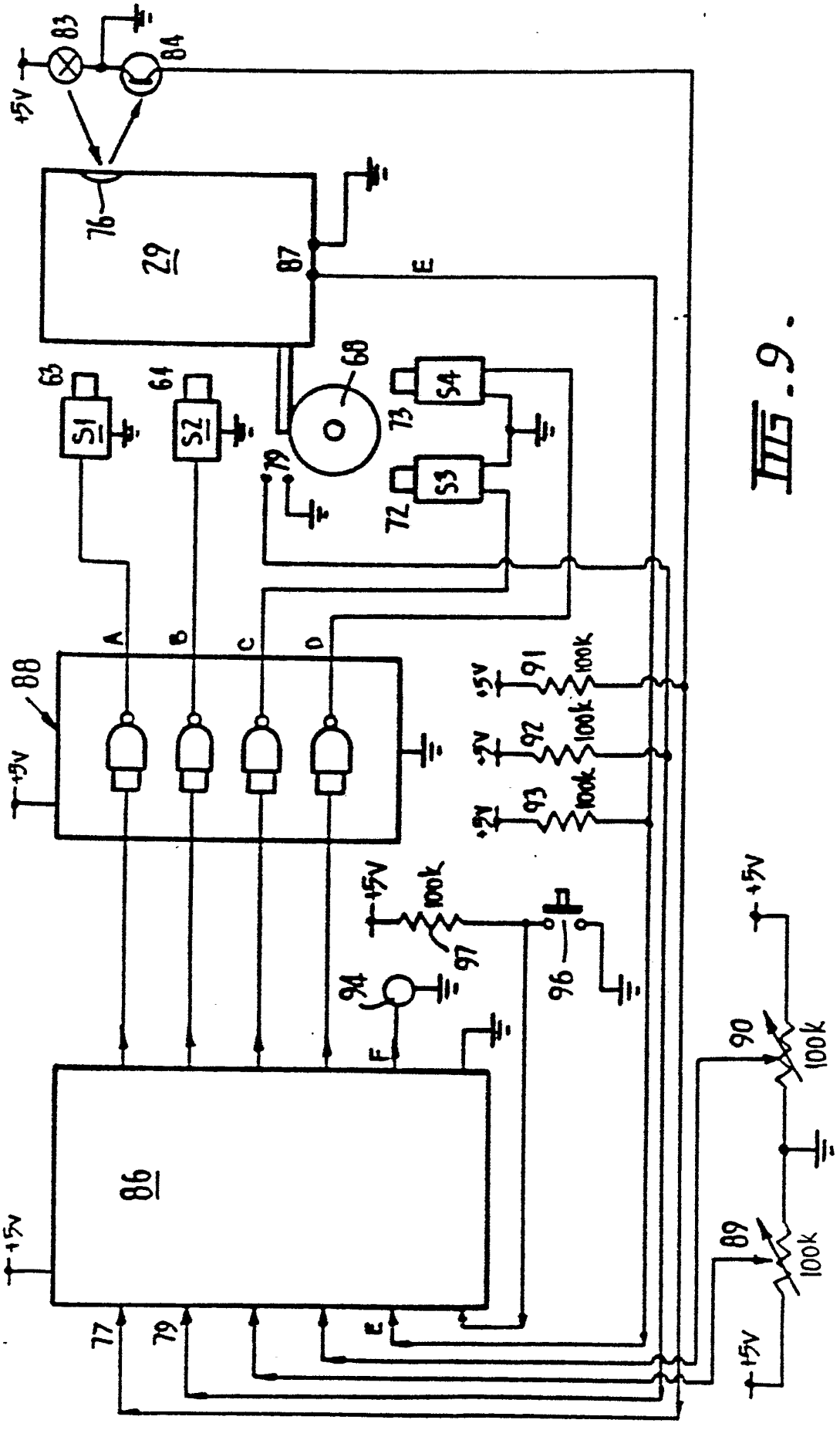


FIG. 8.


+5V
83
84
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87
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S1
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S2
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73
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S3
72
A
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Fig. 9.

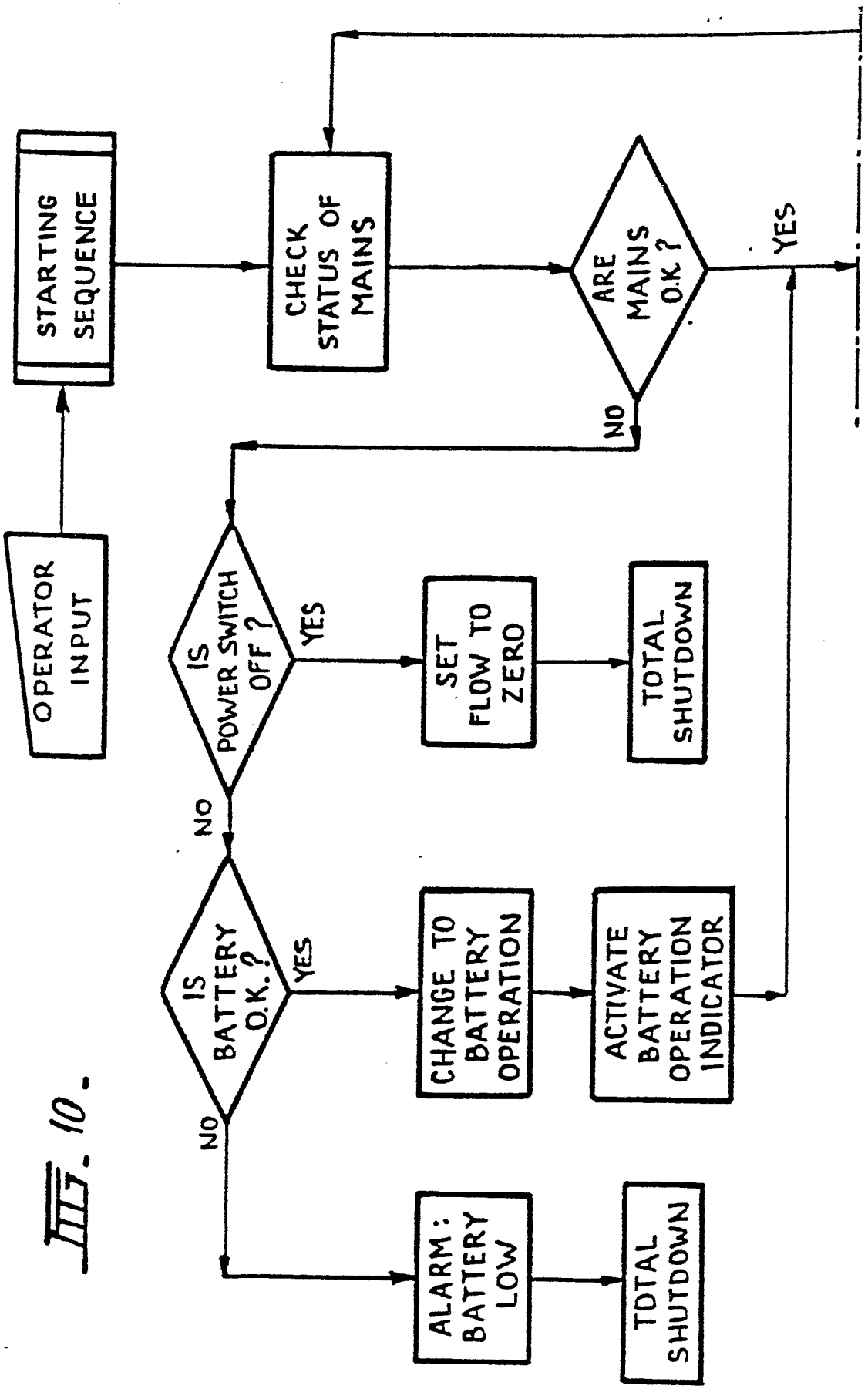


Fig. 10.

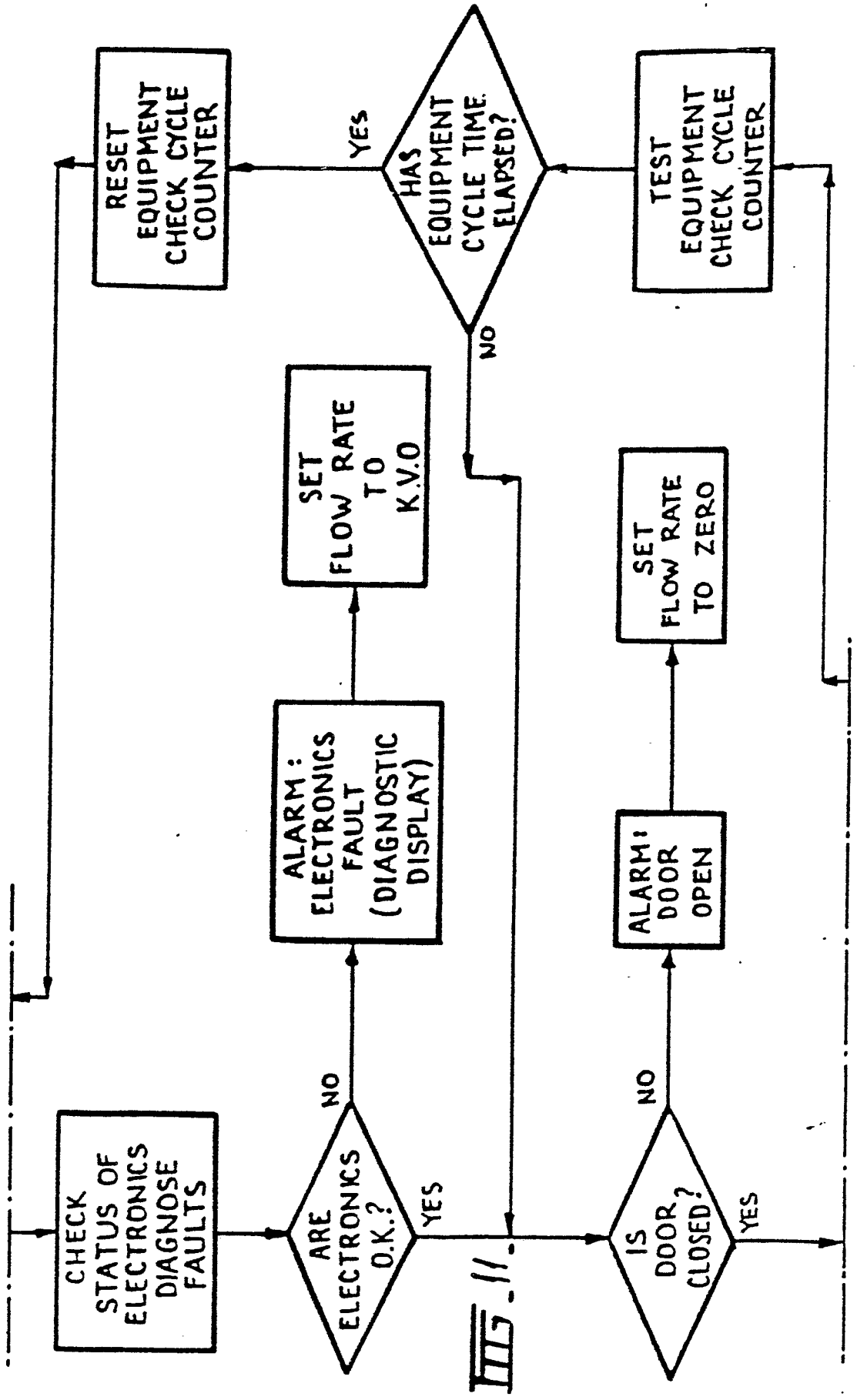


FIG. 11.

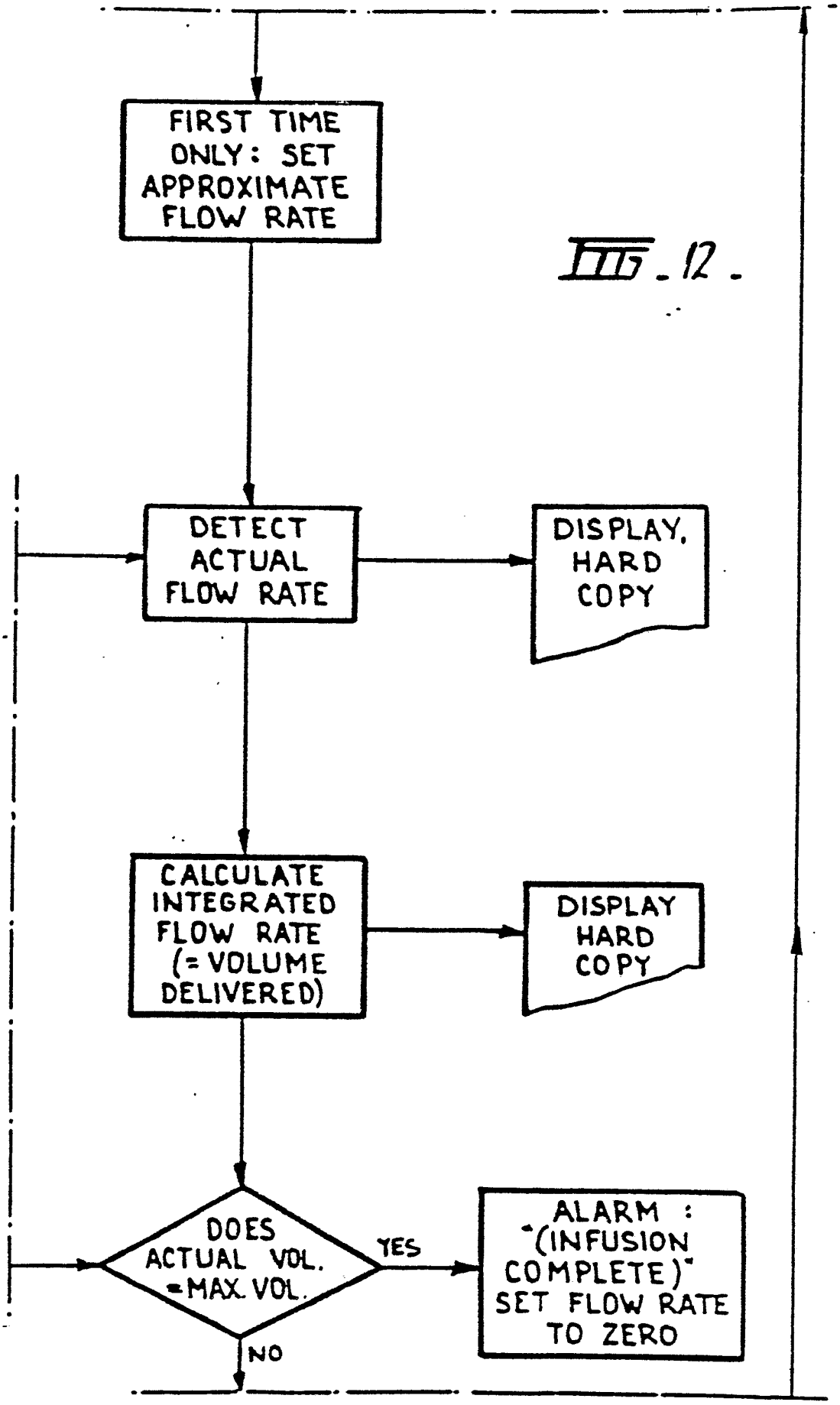


FIG. 12.

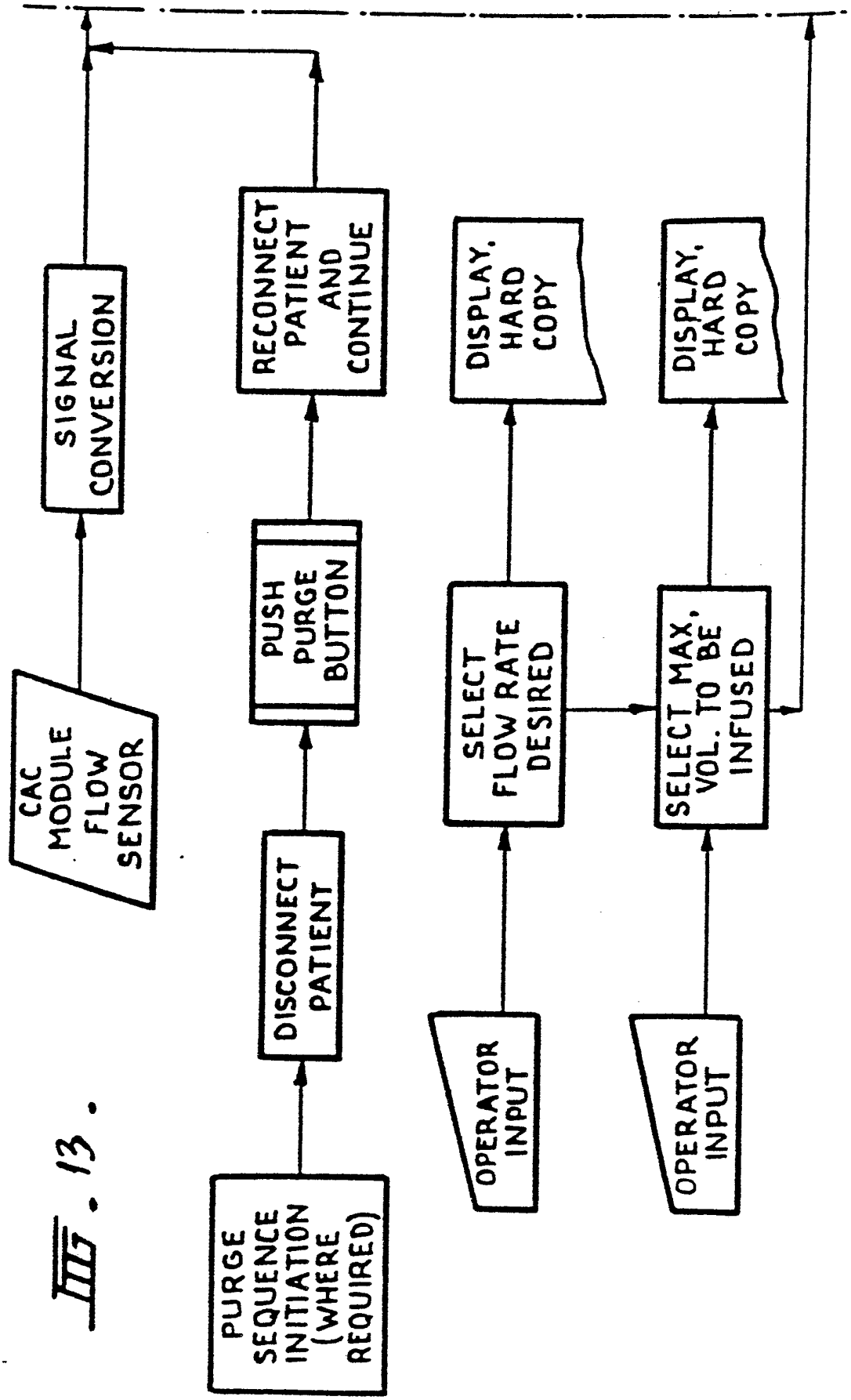


Fig. 13.

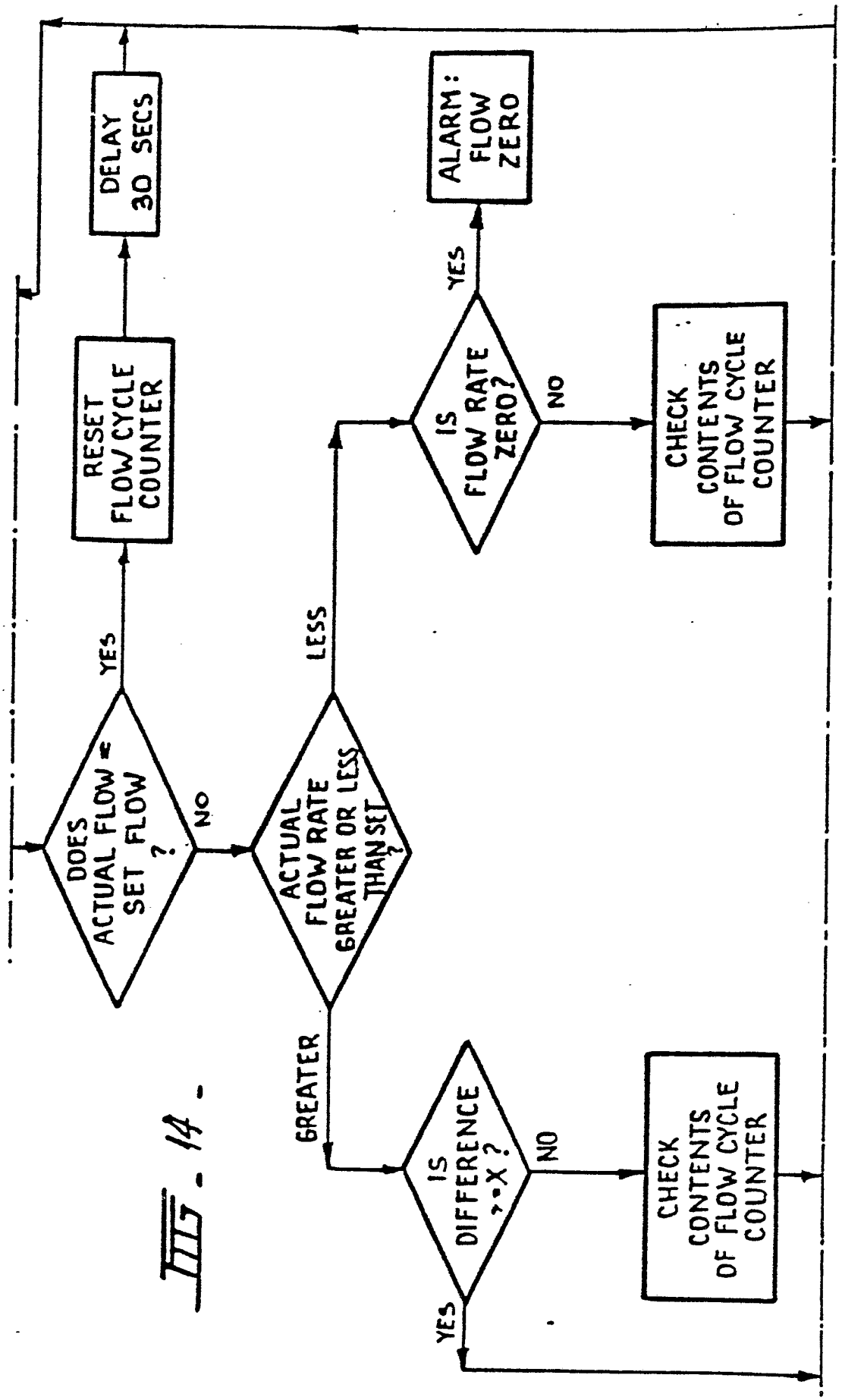


FIG. 14.

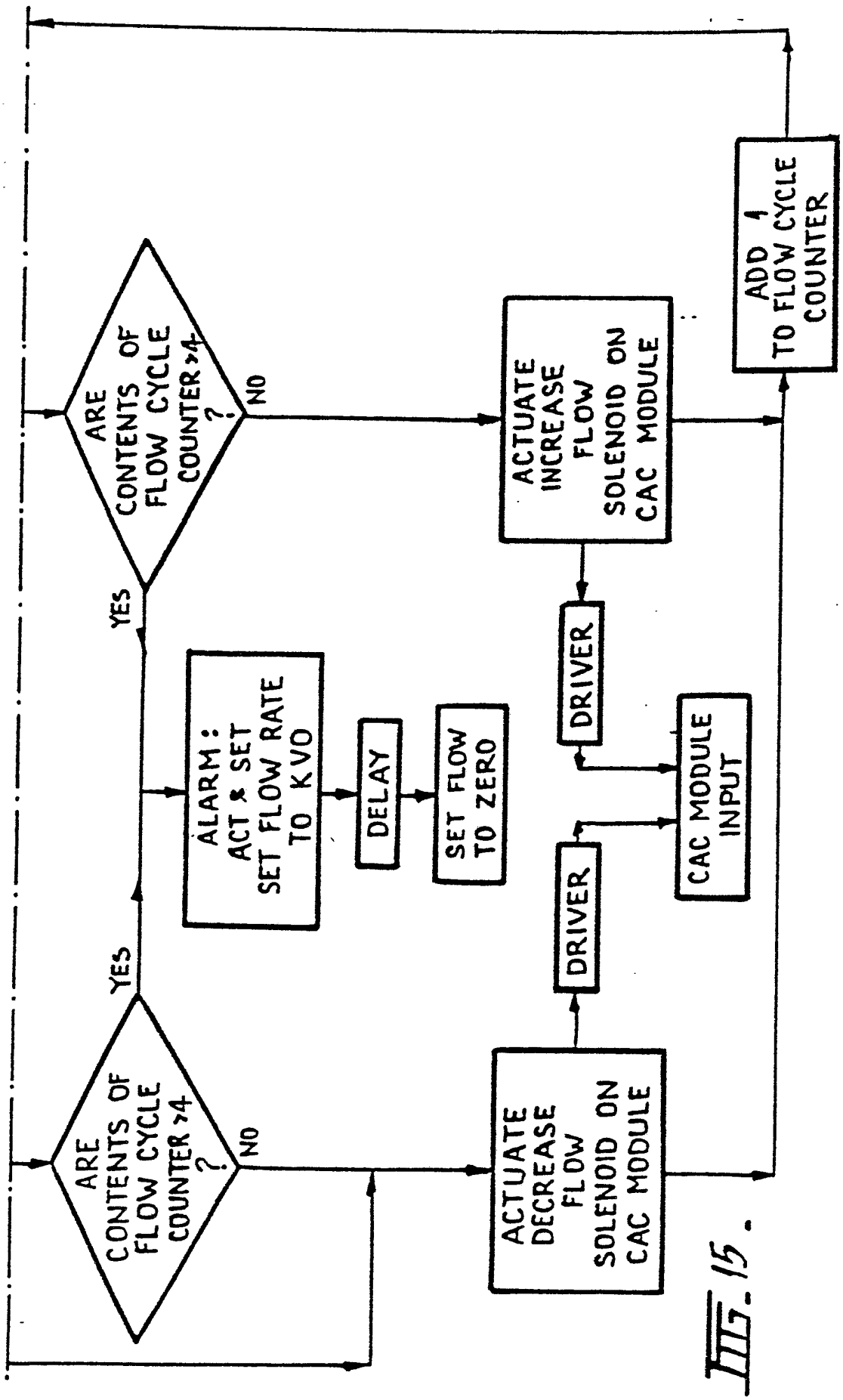


FIG. 15.

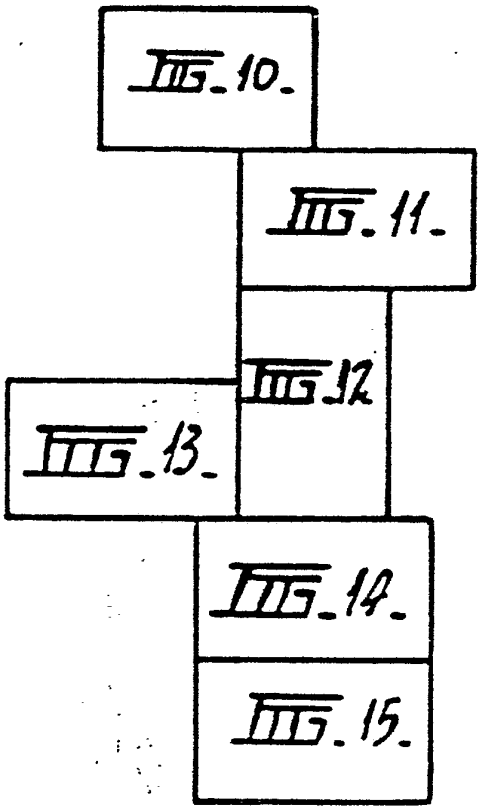


FIG. 16.

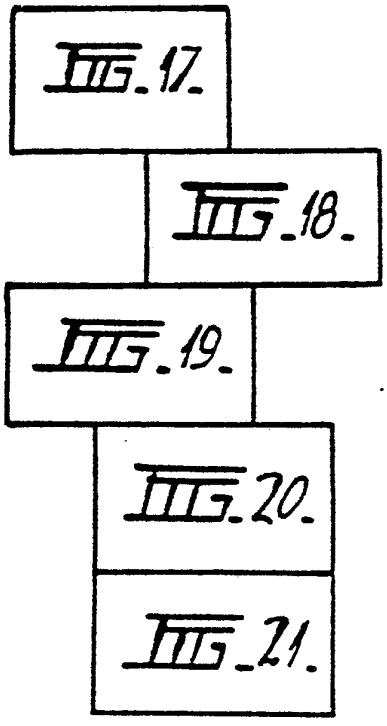


FIG. 22.

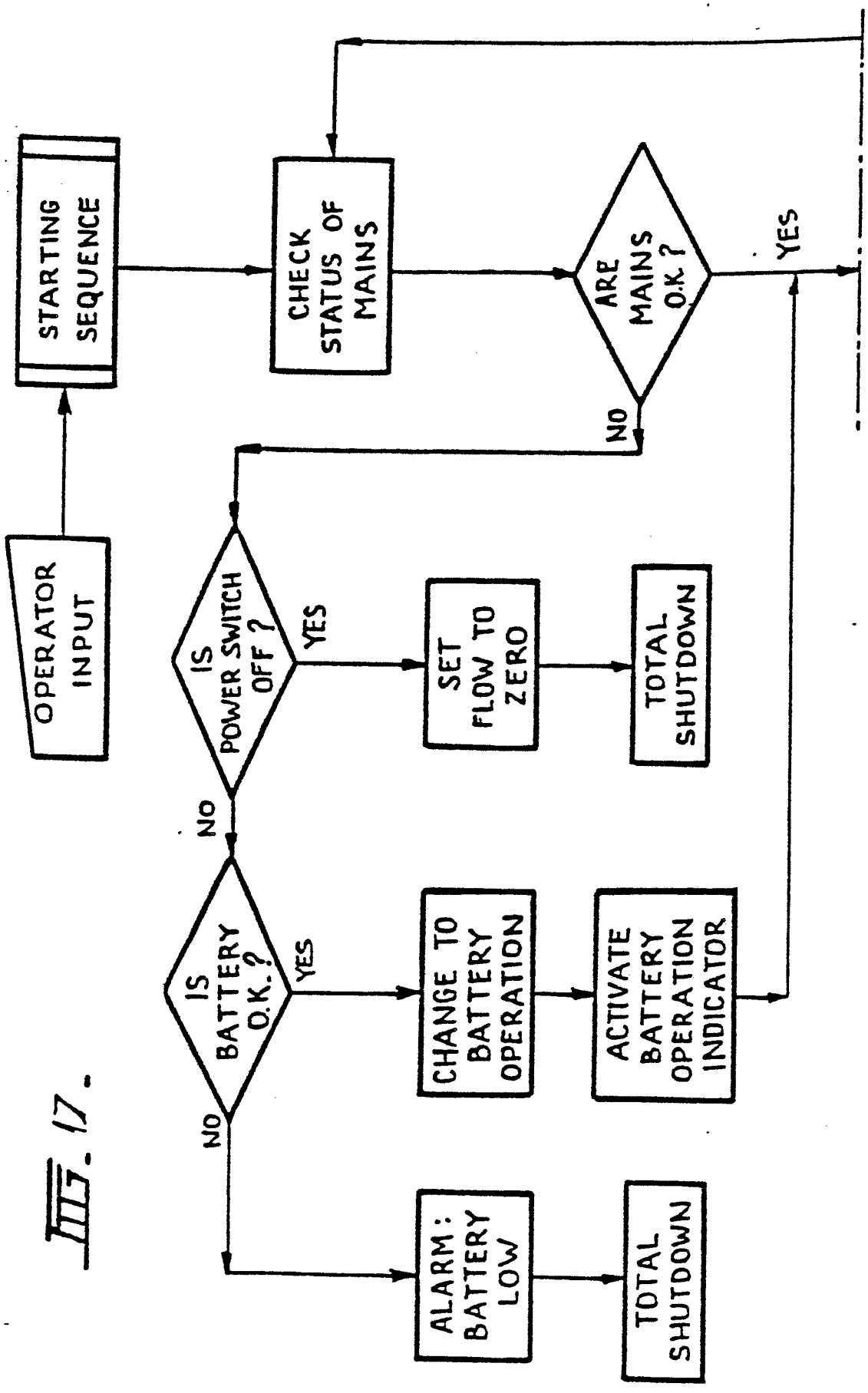


FIG. 17.

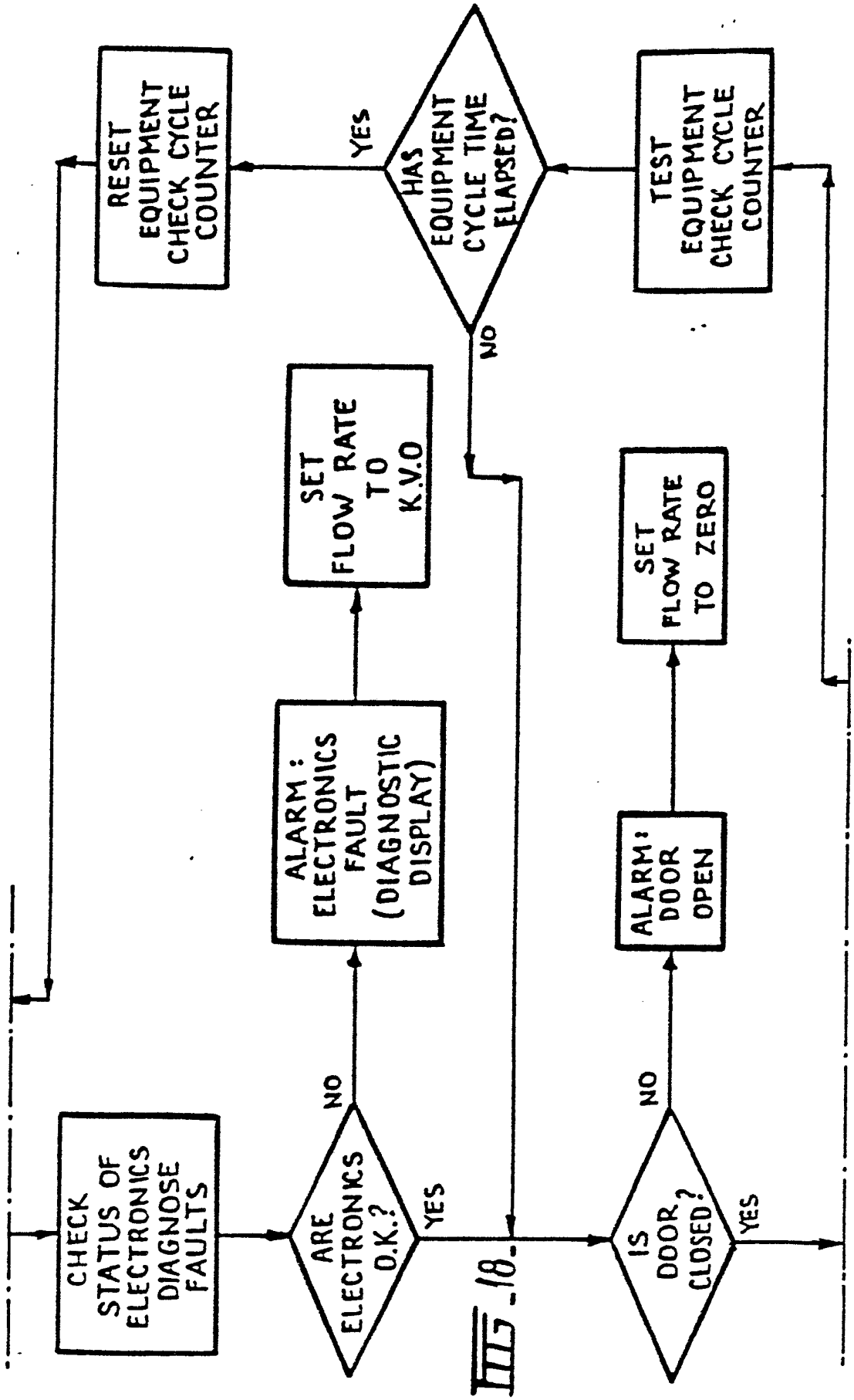


FIG. 18.

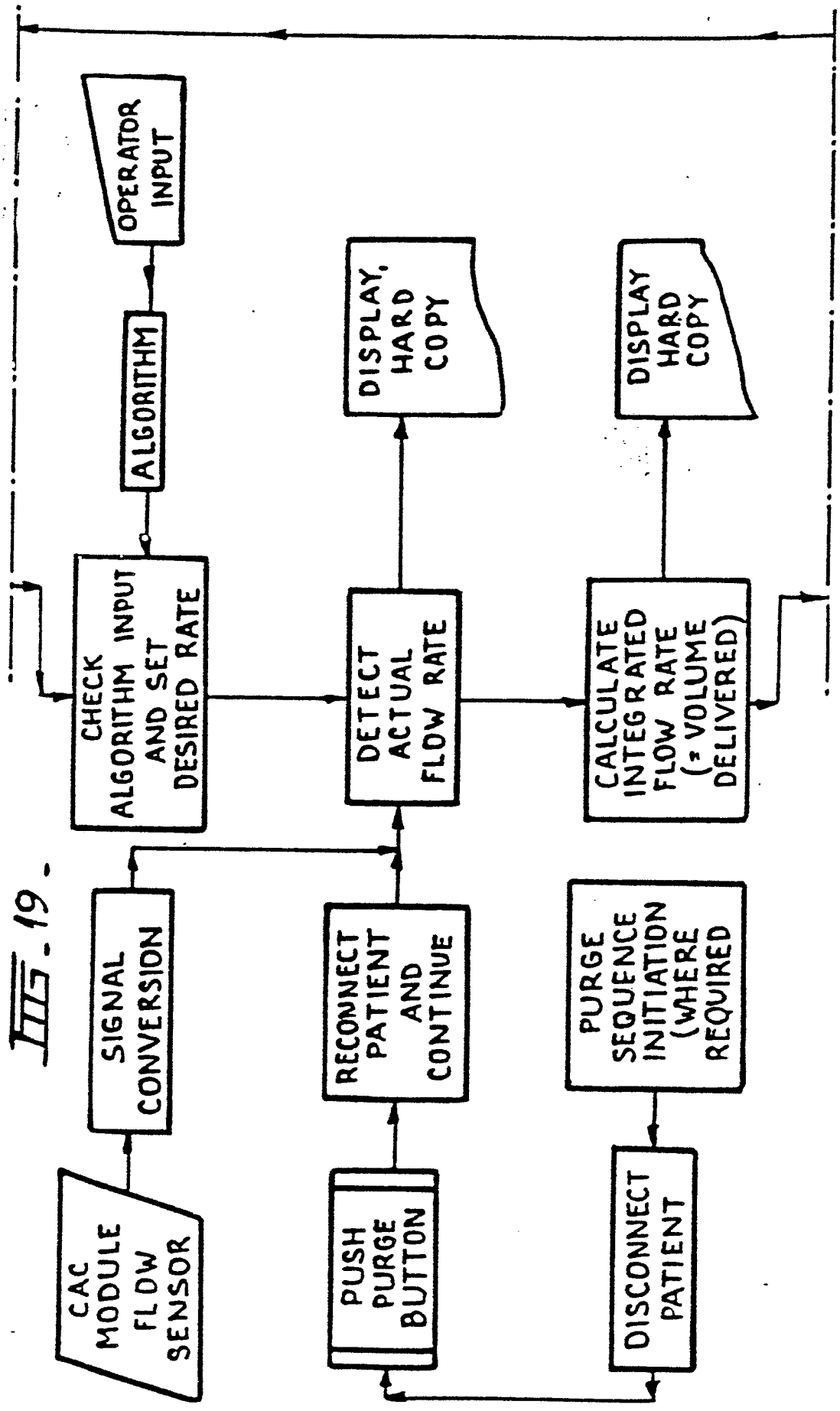


FIG. 19.

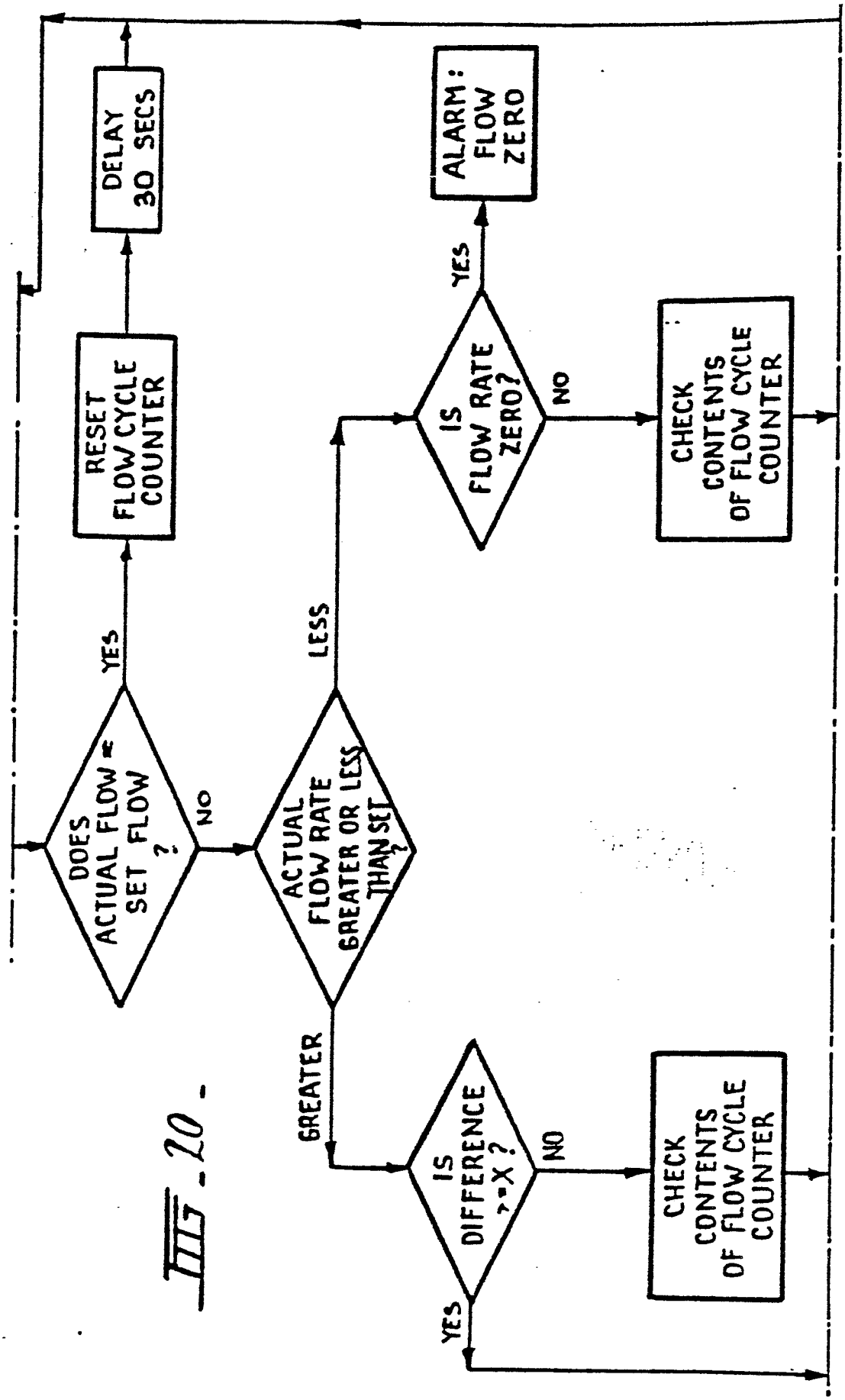


FIG. 20.

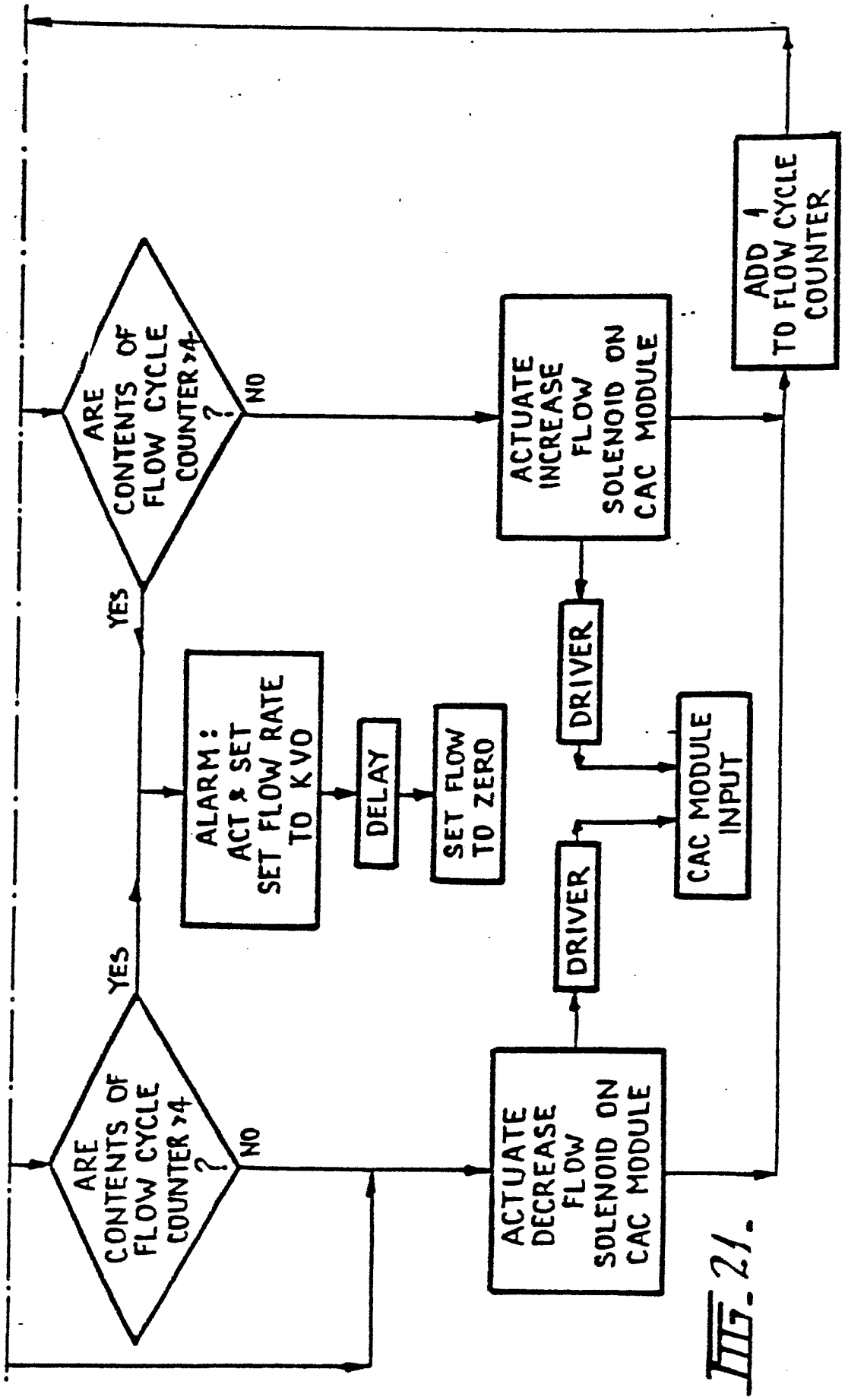


FIG. 21.

STARTING SEQUENCE

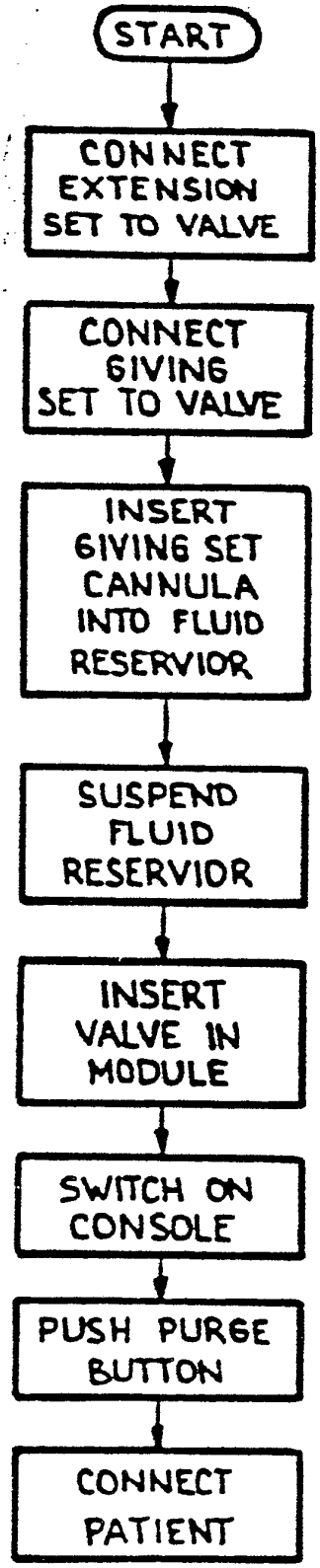


FIG. 23.

PURGE SEQUENCE

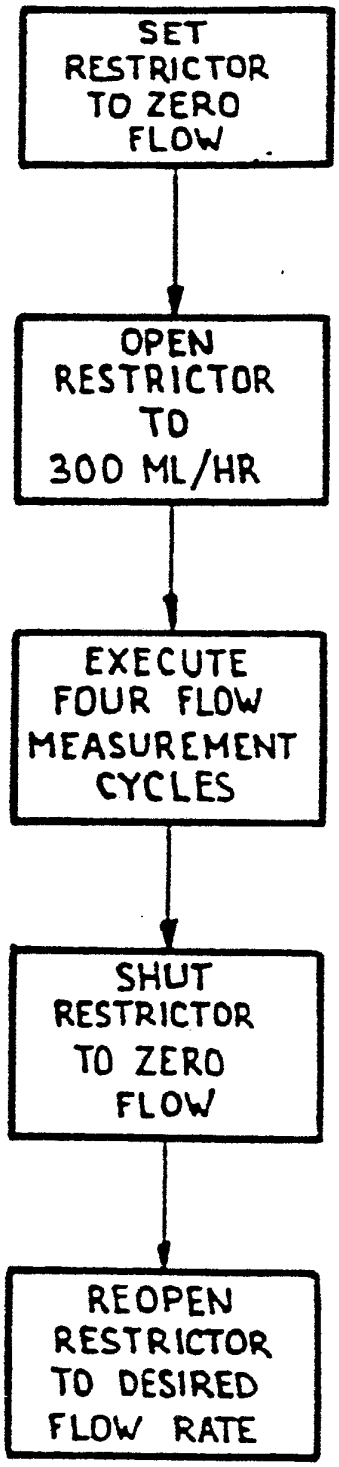
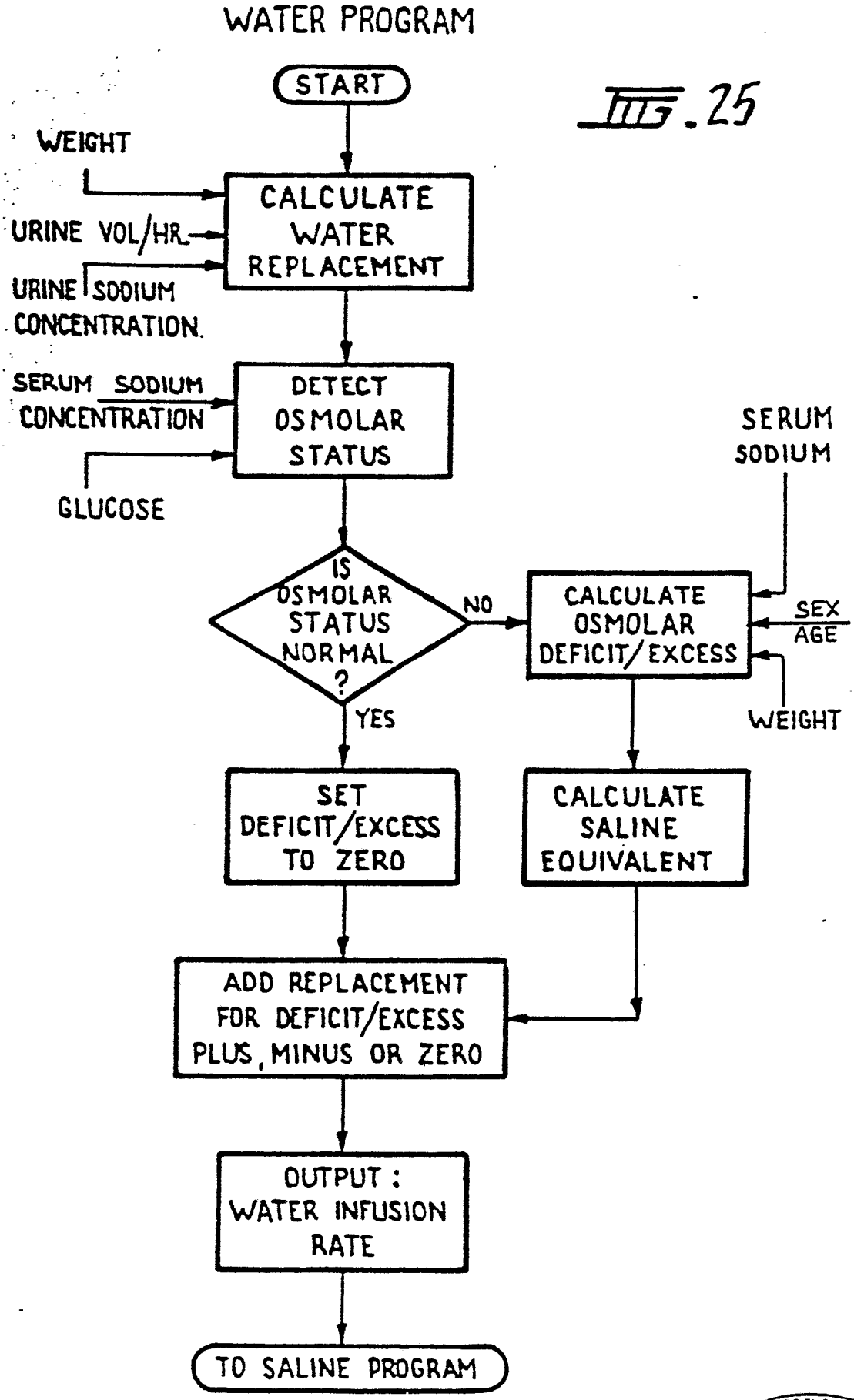


FIG. 24.

FIG. 25



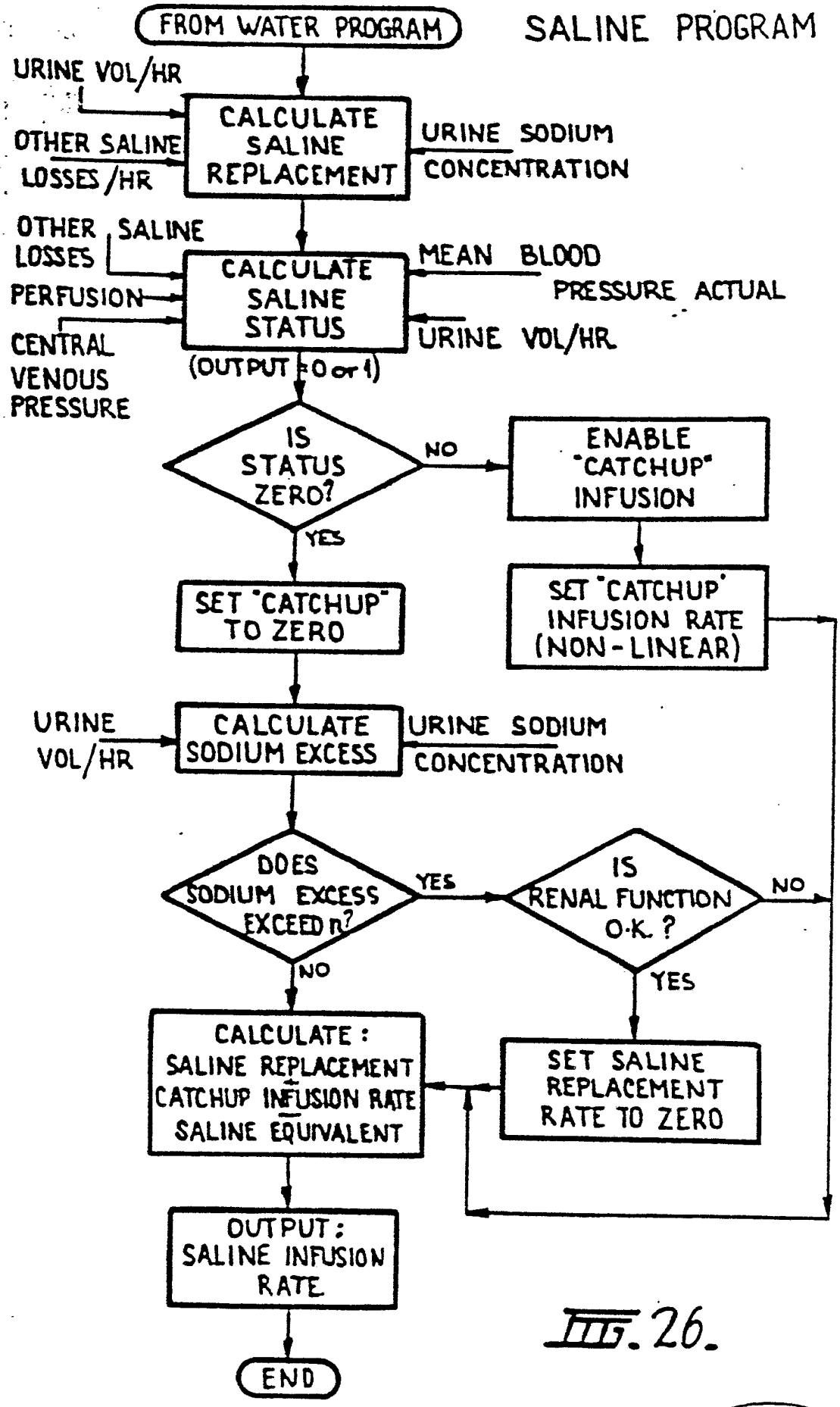


FIG. 26.

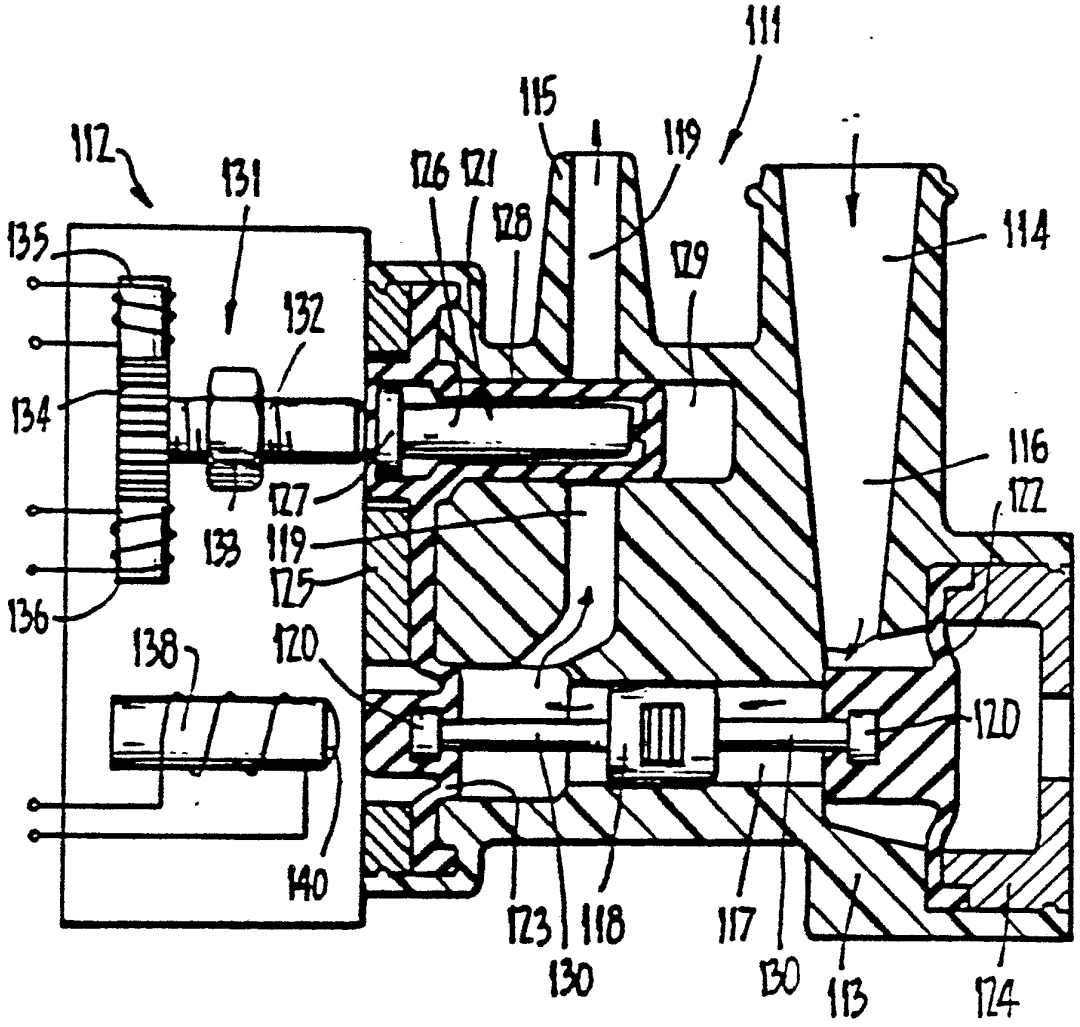


FIG. 27.

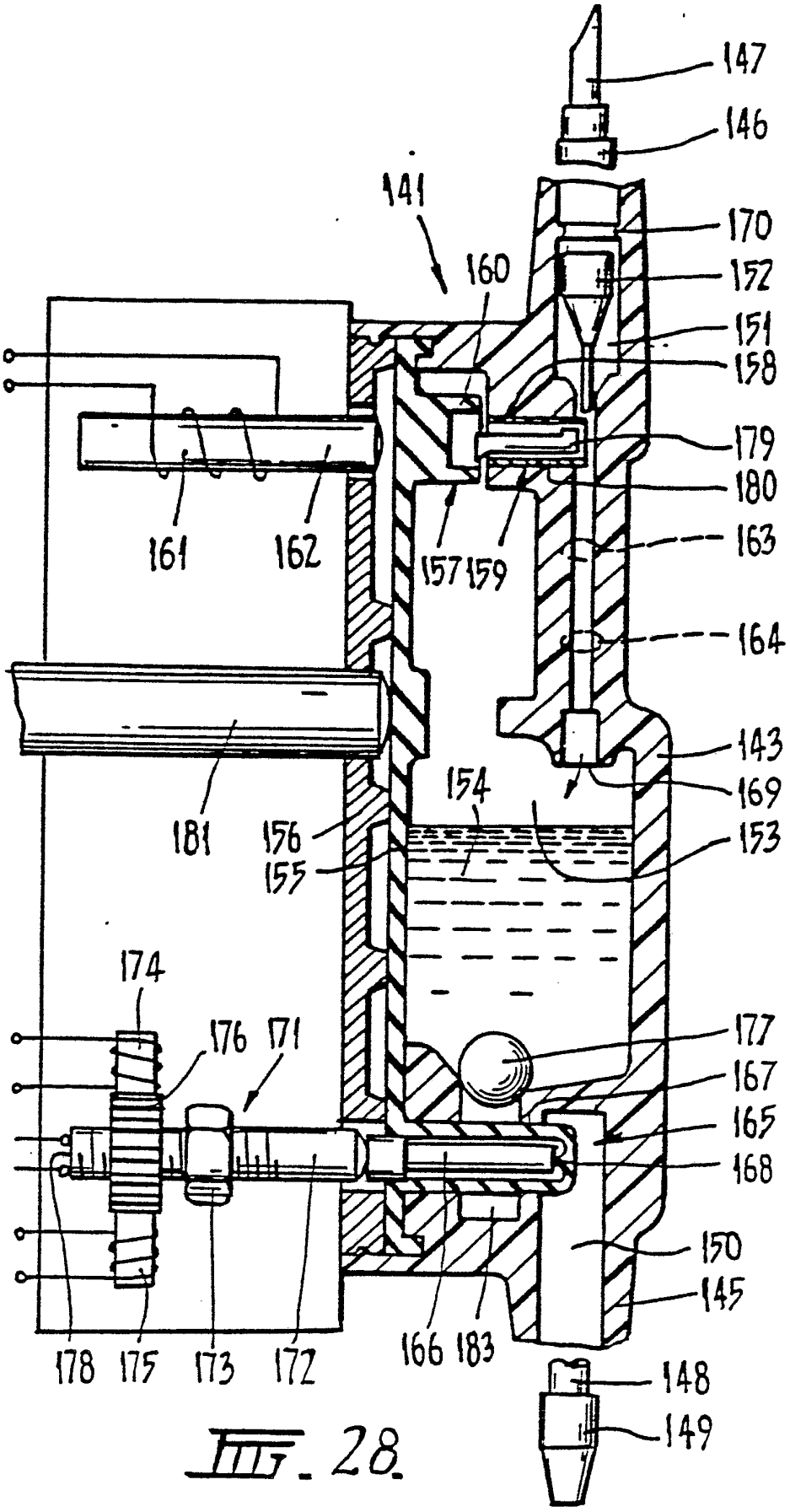


FIG. 28.

INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 80/00053

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl[3]. A61M 5/14, G05D 7/00, F16K 7/16, 31/06

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
IPC	A61M 5/14, 1/02
US Cl.	128 DIG13, 128/214C, 128/214E, 128/214F, 128/214R

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

AU : IPC as above; Australian Classification 87.484, 04.70

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	US, A, 3655095, published 1972, April 11, Kienitz.	(1)
X	US, A, 4037598, published 1977, July 26, Georgi.	(1)
A	GB, A, 1326371, published 1973, August 8, Ivac Corporation (AU 25,685/71)	(1)
A	US, A, 3252623, published 1966, May 24, Corbin.	(1)
A	US, A, 3197068, published 1965, July 27, Corbin.	(1)
A	US, A, 3601124, published 1971, August 24, Petree.	(1)
A	US, A, 4173224, published 1979, November 6, Maax & Edelmann.	(1)
A	US, A, 4094318, published 1978, June 13, Furke, LeFevre & Thomas.	(1)
A	FR, A, 7904072, published 1979, September 14, Bozal Gonalez.	(1)
A	AU, B, 43014/72, published 1973, December 6, S.C. I Systems Inc.	(1)

* Special categories of cited documents: [15]

"A" document defining the general state of the art

"E" earlier document but published on or after the international filing date

"L" document cited for special reason other than those referred to in the other categories

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but on or after the priority date claimed

"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention

"X" document of particular relevance

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
02 October 1980 (02.10.80)	07 October 1980 (07.10.80)
International Searching Authority [1]	**Signature of Authorized Officer [20]**
AUSTRALIAN PATENT OFFICE	R.E.W. MAY.

Form PCT/ISA/210 (second sheet) (October 1977)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers ....., because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.